**UNITED STATES DISTRICT COURT**

**FOR THE DISTRICT OF ARIZONA**

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| **IN RE: Bard IVC Filters Products Liability Litigation,** | ) | MD 15-02641-PHX-DGC |
| **Lisa Hyde and Mark Hyde, a married couple,** | ) | Phoenix, Arizona **October 2, 2018** |
| Plaintiffs, | ) | |
| v. | ) | CV 16-00893-PHX-DGC |
| **C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation,** | ) | |
| Defendants. | ) | |

**BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE**

**REPORTER'S TRANSCRIPT OF PROCEEDINGS**

**TRIAL DAY 11 - P.M. SESSION**

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# I N D E X



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**P R O C E E D I N G S**

(Proceedings resumed at 12:58 p.m.)

(Jury present.)

THE COURT: You may continue, Ms. Helm.

MS. HELM: Thank you, Your Honor.

PAUL BRIANT, PH.D.,

called as a witness herein by the defendants, having been previously duly sworn or affirmed, resumed the stand and continued to testify as follows:

DIRECT EXAMINATION (Continued)

BY MS. HELM:

Q. Dr. Briant, before lunch I think I had asked a question about are you familiar -- the jury has heard about IVC filters made from a substance called Nitinol. And are you familiar with Nitinol?

A. Yes, I am.

Q. And would you explain to the jury what Nitinol is?

A. Sure. So Nitinol's a very interesting material. It's a metal, and it's used in a lot of cardiovascular implanted devices. And it exhibits this special property where you can stretch it much further than a lot of metals, and then it will spring back to its original shape.

Q. And have you had any involvement with Nitinol from a professional point of view? Have you worked with it in your professional career?

A. Yes, I have. I do a lot of work in cardiovascular implanted devices, a lot of which are made of Nitinol, and I've also published papers and given presentations.
Q. And what type of work have you done with cardiovascular Nitinol products?
A. Sure. So, again, this centers around understanding the stresses and strains and the fatigue performance. And it's for devices like stents and heart valves and things like that.
Q. You mentioned you have published articles on Nitinol?
A. I have, yes.
Q. Have you given presentations on Nitinol?
A. I have.
Q. What types of presentations?
A. So they've been at technical conferences, researching Nitinol and understanding its properties.
Q. Were you retained by Nelson Mullins, Mr. Rogers and my law firm, to assist in this case?
A. I was, yes.
Q. Actually, were you retained or was Exponent retained?
A. Exponent was retained.
Q. Okay. And what specifically was Exponent asked to do in this case?
A. So we were asked to review the opinions of Dr. McMeeking, who's the mechanical engineering expert for the plaintiff, and to review the calculations that went into his opinions and to

do our own analysis as needed.
Q. Are you familiar with Dr. McMeeking?
A. I wasn't prior to this litigation, but I certainly am now.
Q. Okay. And who determined what your methodology would be in undertaking the analysis that you were asked to perform in this case?
A. I did.
Q. And what methodology did you use?
A. So the standard methodology we use when analyzing these devices, as I said, calculating the stresses and strains. And we also did laboratory testing to evaluate and verify our calculations.
Q. Is this a methodology you only use in litigation?
A. No. This would be standard for what we do for industrial clients as well.
Q. Okay. So you've talked about you do work for industrial clients and you do work in litigation. Approximately what percentage of your time at Exponent is currently spent on litigation matters?
A. It's about 40 percent of my time.
Q. And can you give us a type -- a sampling of some of the medical devices on which you have conducted analysis either in litigation or in industry?
A. Sure. So as I mentioned, this is things like stents, heart valves, occluders. These are devices that are implanted inside

the body for cardiovascular reasons.
Q. Are you exclusively -- do you exclusively work on medical devices?
A. No. I do -- medical devices is about half of the work I do. I also work a lot in the electronics industry as well, actually.
Q. Can you estimate approximately how many medical devices you've analyzed, tested, or reviewed as part of your work in Exponent over the last 10 years?
A. So I don't have an exact number, but well over a hundred. It's what I do day in and day out.
Q. In your work for industry, has any of your analysis been presented to the FDA as part of a device submission for clearance by the FDA?
A. Yes. Many times. And I also assist companies when they have questions from FDA reviewers and things like that.
Q. Okay. To perform your analysis in this case, were you provided documents?
A. Yes, I was.
Q. And what documents were you provided?
A. Expert reports from other experts, deposition transcripts, Bard documents for doing the submission process, 510(k)s, things like that.
Q. Were you provided materials regarding the development of the Recovery, G2, G2X, and Eclipse filters?

A. Yes, I was.
Q. Were you provided testing materials; test protocol and test results from Bard?
A. Yes, I was.
Q. And did you -- I'm sorry. Let me -- did you review the documents referenced by Dr. McMeeking in his reports and depositions?
A. I don't know if I reviewed all of them, but I certainly reviewed most of them.
Q. Okay. And, again, as part of your work, you've talked about analysis. Did you also perform testing, physical testing on any of Bard's IVC filters?
A. Yes. We performed experimental bench testing on filters in our laboratory.
Q. And did you do that testing yourself?
A. So I have a team that helps me, so it was a combination of technicians as well as other engineers at Exponent.
Q. And were some of those other engineers Ph.D.s also?
A. Yes. They all were.
Q. Do you know if any of them got a B in Greek Mythology?
A. I'll ask.
Q. Has Exponent charged my law firm for the testing, analysis, and other efforts that you've performed in this case?
A. Yes, we have.
Q. Are you an employee or an owner of Exponent?

A. I'm an employee.
Q. Do the billings to Exponent reflect only your time, or is it the time from everyone that's been involved from Exponent?
A. It's the whole team.
Q. And how much has Exponent billed my law firm for your analysis relating to the Bard IVC filters?
A. So my bill rate is 425 an hour.
Q. And do you know how much total Exponent has charged my law firm?
A. It's about $700,000, I believe.
Q. And do you get paid based on your hourly rate or the work that you do, or are you simply a salaried employee?
A. I get a salary.
Q. Okay. As the work -- as a result of the work and investigation you've done in this case, have you reached any opinions?
A. Yes, I have.
Q. Can you tell the jury what those opinions are?
A. Sure. So as you heard from Dr. McMeeking, who's the engineering expert for the plaintiff, he renders a series of claims and criticisms about the Bard filters, both about the design of the filters as well as the testing and analysis that Bard did during the design process.

And so my opinions boil down to three main things. Number one is that the calculations that Dr. McMeeking

performed that underlie or the foundation for his design opinions, that those calculations are unreliable. And this is due to the simplifications that were made in those calculations as well as the assumptions that were fed into the analysis. And as you'll see, those assumptions were often beyond the limits of what the body can do. So that's number one.

Number two --

Q. Do you have another opinion?

A. Yes. Number two is, although Dr. McMeeking criticizes the Bard testing, the testing did consider all the relevant complications that are known to occur with IVC filters. And even though Dr. McMeeking provides these criticisms, he doesn't put forth any analysis or engineering basis for alternative test methods or alternative designs.

And lastly --

Q. I'm sorry. Do you have a third opinion?

A. Yes, I do.

Lastly is that the Simon Nitinol filter, which you've heard about, from an engineering perspective, is not an alternative design. And this is because it lacks the retrievability of the Bard filters.

Q. Did you prepare a summary of your opinions for us to review?

A. Yes, I did.

MS. HELM: Your Honor, at this time I --

Would you pull up 7944?

That's not the right one. 7944. We'll just go on if we don't have it.

BY MS. HELM:

Q. As part of your work, did you review some Bard filters, actually physically hold, test Bard filters?

A. Yes, I did.

Q. What did you do with those filters that you examined?

A. So we used those filters for our laboratory testing, and we did that to validate our calculations to make sure that they actually represent the real world and are consistent with reality.

Q. Did you review any materials specific to Mrs. Hyde?

A. Just other expert reports.

Q. Did you have Mrs. Hyde's filter available to you to test or review?

A. No.

Q. Do you know what type of filter Mrs. Hyde has?

A. My understanding is it was a G2X or an Eclipse filter.

Q. In your report --

MR. O'CONNOR: Objection, Your Honor. Move to strike. That was not disclosed.

MS. HELM: Your Honor, I think the next question will clarify it. I was about to ask him specific --

THE COURT: I don't think he stated an opinion. He

just said he understood it was one or the other.

MR. O'CONNOR: Well -- and that's not disclosed.

THE COURT: Well, I think that's background. I don't think that's expert testimony.

So I'm going to overrule that objection.

BY MS. HELM:

Q. Dr. Briant, did you identify Ms. Hyde's filter as a G2X in your report?

A. Yes, I did.

Q. And why did you do that?

A. That was based on the information I had at the time.

Q. Are you aware of the types of events that occurred with Ms. Hyde's filter?

A. Yes, I am.

Q. And what do you understand?

A. So my understanding is that it tilted by about 2 to 4 degrees, that it had a caudal migration of about 5 millimeters, and that there was perforation and then an arm that fractured and subsequently went to her right ventricle.

MR. O'CONNOR: Again, Your Honor, I object. Those opinions are not in his report.

THE COURT: Ms. Helm, where are those in the report?

MS. HELM: His July 20, 2017, report. It's page 3, Section 2.1.

THE COURT: Objection is overruled. It's on page 3,

Section 2.1 of the July report.

MR. O'CONNOR: I understand, but the specifics he testified to are not there.

THE COURT: Migration, fracture, embolization. It's all mentioned there.

MR. O'CONNOR: The degrees.

THE COURT: Pardon?

MR. O'CONNOR: The degrees and the measurements were not in his report.

THE COURT: Well, you didn't object -- oh, I see. You're saying the specific degrees that he mentioned.

MR. O'CONNOR: Yes.

THE COURT: Are those in the report?

MS. HELM: No, Your Honor, they're not.

THE COURT: Okay. The jury should disregard the degrees testified to and the length of the migration.

BY MS. HELM:

Q. Dr. Briant, are you aware that there's been testimony in this case that the degree of tilt of Ms. Hyde's filter was approximately 2 to 4 degrees?

A. Yes, I'm aware.

Q. Are you aware that there's been testimony in this case that the degree of caudal migration of Ms. Hyde's filter is approximately 5 millimeters?

A. Yes, I'm aware.

Q. Okay. And prior to that testimony in this case, you were aware -- were you aware that there was indication of possible perforations and that one arm had fractured and moved to her heart?
A. Yes, I'm aware.
Q. Thank you.
Okay. A minute ago, before I had some technical difficulty, we talked about a slide that you had prepared that summarized your opinions.
MS. HELM: And can you pull up 7944, please?
BY MS. HELM:
Q. And can you see that, Dr. Briant?
A. Yes, I can.
Q. Is that the slide that you prepared that summarizes your opinions in this case?
A. Yes, it is.
MS. HELM: Your Honor, at this time I would tender 7944 for demonstrative purposes only.
MR. O'CONNOR: Objection. The summary is not disclosed in the report, Your Honor.
THE COURT: Is this in the report?
MS. HELM: Yes, Your Honor. It's a -- it is a compilation of diagrams from his report that are on -- his reports: His April 2017 report, page 4, Section 3.1, Item 1; his July 2017 report, page 7, Section 5, paragraph --

THE COURT: Hold on just a minute. I need to look at them.

There's no diagram on page 4 of the April report.

MS. HELM: Your Honor, if you -- April 2017 report, page 9, Figure 2B, and page 18, Figure 11.

THE COURT: All right. All of those diagrams are found on those pages, portions of them.

MR. O'CONNOR: I'm not objecting to the diagrams. I'm objecting to the Opinions Summary.

THE COURT: You disagree with the opinions that are --

MR. O'CONNOR: Pardon me?

THE COURT: Do they accurately summarize what's in the report? Is that your objection, Mr. O'Connor?

MS. HELM: Your Honor, I have cites to the opinions.

MR. O'CONNOR: Well, just to move things along, we'll withdraw the objection.

THE COURT: All right. You may show 7944 as a demonstrative.

MS. HELM: Thank you.

BY MS. HELM:

Q. Dr. Briant, is this the demonstrative or the exhibit you prepared to further explain your opinions in this case?

A. Yes, it is.

Q. Okay. And going back to your first opinion, would you remind the jury what your first opinion is, please.

A. Sure. So my first opinion relates to the calculations that Dr. McMeeking performed and them being unreliable due to the simplifications that were incorporated into the opinions and the assumptions that were used.

Q. And can you explain to us why it is your opinion that Dr. McMeeking used incorrect assumptions? And let me back up.

This is in his -- is this in his analysis of strain of the filter?

A. That's correct.

Q. Okay. And can you explain to us why it's your opinion that Dr. McMeeking used incorrect analysis -- incorrect assumptions in his analysis of the strain of the Bard IVC filters?

A. Sure. So Dr. McMeeking made -- only incorporated into his analysis a single arm of an IVC filter. And that's what's shown on the right-hand side of the slide. So the figures depict the differences between the two analysis approaches or methodologies.

So on the right-hand side we have, from Dr. McMeeking, he had just a single arm incorporated explicitly into the analysis. And actually, it was just a portion of that. It was the upper portion above the elbow.

Q. And why do those limitations by Dr. McMeeking of only analyzing the portion of the arm above the elbow matter?

A. Sure. So to make that simplification, he'd have to make assumptions about how the filter interacted with the IVC. So

what he assumed was essentially that the IVC was infinitely stiff or perfectly rigid, and so that the motion of the IVC would not be affected by the presence of the filter, meaning that the forces that the filter pushes back on the IVC would not come into play.

In addition, he assumed that wherever the filter touched the IVC, that it was essentially locked, and so the filter just had to move wherever the IVC went, and he prevented rotation there. And he had to make assumptions about this interaction in order to simplify the analysis to only include that portion of the arm.

Q. Beyond his analysis, did Dr. McMeeking conduct any bench testing relating to his analysis of the strains in the Bard IVC filters?

A. No, he did not.

Q. Now, did you perform your own analysis?

A. Yes, we did.

Q. And did you only analyze one arm of an IVC filter?

A. No. And that's depicted in the middle column there, where -- so in the analysis, we have the entire filter, all six arms and all six legs. And then what we would do is we would take that filter and we'd crimp it down and we would deploy it into the surrounding soft tissue.

So we had in the model the surrounding tissues, and that's shown on the bottom center, where the blue is the IVC,

the green is the surrounding soft tissues, and orange represents a vertebra.

So we incorporated the environment that the filter lives in rather than just including the filter and making assumptions about the interaction between the filter and the IVC.

Q. And did you make assumptions in performing your analysis?

A. So we -- we, by incorporating the environment that the filter lives in, we didn't have to make the assumptions that Dr. McMeeking made. So we could actually calculate this interaction and understand what effect the filter would have on the IVC and back and forth.

Q. You mentioned you included the surrounding tissues and what was going on with the IVC. Would you explain to us what you mean?

A. Sure. So the IVC -- or, sorry -- the filter, as you know, is implanted in the abdominal region, and so it's in the IVC and it's surrounded by digestive organs and things like that. So the -- these materials have certain properties. The IVC generally has the stiffness of about a rubber band as opposed to infinitely stiff, as we talked about. And the surrounding soft tissues are also soft, the digestive organs, and -- at least on me, they're soft in that general region.

Q. And you mentioned -- I'm sorry.

Did you prepare a demonstrative that would help

explain the impact of the assumption you made regarding the surrounding tissue?

A. Yes, I did.

MS. HELM: Would you pull up 7813, please.

Your Honor, at this time I would move to admit 7813 for demonstrative reasons only.

MR. O'CONNOR: No objection for demonstrative.

THE COURT: All right. You may display it for demonstrative purposes.

MS. HELM: Thank you.

BY MS. HELM:

Q. Dr. Briant, would you explain to the jury what is depicted on 7813?

A. Sure. So this is a -- on the left, we have a section of a CT scan. So this was taken from a patient. And what we're looking at is a cross-section of the abdomen.

That bright region in the middle, that's a vertebra. You can see it labeled in the picture there. The IVC is above and a little bit to the left. It's where those yellow circles are. And this one has a filter in it. And then surrounding that is the digestive tissues that you can see.

And then we -- this shows the motivation for the model. So we take this and we poured it over to the model that's on the right. This is what was actually done in the analysis, where we have the IVC in blue, the surrounding soft

tissues in green, and we incorporate the vertebrae that's nearby. And so this allows us to actually model the environment of the filter in addition to the filter itself.
Q. As part of your work, you did not assume that the IVC was stiff; is that right?
A. Correct. It -- we included a stiffness for it, but it's not infinitely stiff the way Dr. McMeeking assumes. As I mentioned, it's about the stiffness of a rubber band.
Q. As part of your work in studying mechanical engineering issues, are you familiar or do you have to become familiar with medical literature that substantiates or supports your assumption about the tissues surrounding the IVC, the lack of stiffness?
A. Yes.
Q. And how do you validate that?
A. Sure. So there are two ways that this is motivated. Number one is that people have actually taken IVCs and pulled on them and measured their properties, so they've actually measured what we call the stress-strain response. And so that's -- that's what we incorporate into our analysis.

In addition, studies have also looked at the diameter of the IVC in patients that have filters deployed. And what they've found is that at the location of the filter, the IVC is bigger than above or below it, indicating that the IVC is responding to the forces from the filter as well as the

surrounding tissues.
Q. And when you mention studies, are you referring to studies in medical literature?
A. They're in the published literature, yes.
Q. And was that the source of your information for your analysis of the stiffness or the lack of stiffness of the IVC and the other organs in the body?
A. That, and some of the data as reported in textbooks as well.
Q. Thank you.
Can you explain to the jury what hyperelastic stress-strain means?
A. Sure. So this is -- hyperelastic is a formulation that we use to represent the stress-strain response for biological tissues.
Q. And did you prepare a demonstrative that explains hyperelastic stress-strain?
A. I did, yes.
MS. HELM: Scott, would you pull up 7945, please.
BY MS. HELM:
Q. And, Dr. Briant, is this the demonstrative that you prepared to help explain hyperelastic stress-strain response?
A. Yes, I did.
MS. HELM: Your Honor, at this time I tender 7945 for demonstrative reasons only.

MR. O'CONNOR: No objection for demonstrative purposes, Your Honor.

THE COURT: You may display it.

BY MS. HELM:

Q. Dr. Briant, can you explain this slide to us?

A. Sure. So, yes, we're getting "mathy" here.

So this is a plot showing the stress-strain response for the IVC. And so what we have on the horizontal axis is strain. And that's a measure of the deformation or how much the material has response to a given load, how much it's deformed.

On the vertical axis we have stress, and that's a measure of how much force is applied, so the intensity of the force. When you push on something or pull on it, you apply a force, and that's what's plotted on the Y axis, the vertical axis.

And then you can see the response of the tissue. And so initially it's soft. It has this low modulus, this low slope here. And then eventually it stiffness up.

And this is due to the collagen fibers that are in your tissue, where initially they're relatively disorganized, and then as you pull on them, they become more and more organized and aligned. And that causes this stiffening that you see later in the curve where it's harder to pull on.

Q. Let me ask you just a couple questions. There's some

references on here, and I want to make sure we understand them.

There's a reference to "modified data from Fung." What is that?

A. Sure. So Fung is the author of a textbook that we acquired the experimental data from.

Q. And there's a reference to the "Marlow fit." What is that?

A. So Marlow's a particular formulation of the hyperelastic, so it's a mathematical fit that we use to fit the data that we put into the model.

Q. In doing your stress-strain analysis here, did you take into account this hyperelastic response of a person's IVC that you talked about?

A. Yes. So this is directly incorporated into the analysis. So this would be how the IVC itself responds to load, and this was in the analysis.

Q. Okay. And how does your consideration, taking into account the hyperelastic response of the IVC, make your assumptions and calculations different from those of Dr. McMeeking?

A. So as I mentioned, Dr. McMeeking assumed that the IVC was -- it was infinitely stiff, that it would not respond to the forces from the filter in any way. And so rather than making that assumption, we wanted to actually evaluate that. And so we made this model that has the IVC and the surrounding soft tissues and used these values from literature for the properties and were actually able to calculate that

interaction.
Q. And is that an important difference, this consideration of the hyperelastic response of the IVC to the filter?
A. Yes, by -- the assumptions that were made, assuming the IVC is infinitely stiff, would result in higher strains than the filter would actually occur. Because you're not actually accounting for the interactions directly, but you're making this assumption of a very stiff vessel.
Q. You've told us about your difference in your analysis from Dr. McMeeking's as it relates to the actual IVC itself. Did you also have -- did you also consider differences or make different assumptions relating to Nitinol than those made by Dr. McMeeking?
A. Yes, I did.
Q. And did you prepare a demonstrative that would help you explain your analysis of Nitinol?
A. I did, yes.
MS. HELM: And would you pull up 7677, please.
Your Honor, at this time I tender 7677 as a demonstrative.
MR. O'CONNOR: No objection for the purposes of demonstrative.
THE COURT: You may display it.
BY MS. HELM:
Q. This is entitled -- or, Dr. Briant, would you read the

title of this slide to us, please.
A. Sure. So it's the Nitinol Constitutive Relationship.
Q. What is Nitinol constitutive -- I can't even say it. What is the Nitinol constitutive relationship?
A. Sure. So, again, this is the stress-strain response of the Nitinol. So rather than looking at the tissue now, we're looking at the Nitinol metal that makes up the filter.

And so as I mentioned, Nitinol is this very interesting material that has this superelastic response. And so what we're looking at, again, is very similar to the previous slide, where on the horizontal axis we have strain, the deformation, and on the vertical axis we have stress.

And Nitinol goes through what we call a phase transformation, where you start to load it up and then it stretches a lot, so it moves a lot along the horizontal axis. And then it completes the phase transformation and you get this later stiff response.

And so this is the property that allows the Nitinol to spring back after you've reached its deployment location for the device.
Q. And is that quality of Nitinol that allows it to spring back, is that sometimes referred to as superelastic?
A. Correct. That's what it's called.
Q. Did you take into consideration the superelastic or the springback of Nitinol in your analysis?

A. Yes, we did.
Q. Did Dr. McMeeking include that property in his analysis?
A. In his strain analysis, he did not. He just modeled it as what we call linear elastic, which is basically just the beginning part of the curve.
Q. Is it well known in the mechanical engineering and material sciences that Nitinol has this superelastic property?
A. Yes. It's what makes Nitinol Nitinol.
Q. Do you believe it's possible to accurately model the stresses and strains of Nitinol without taking into account the superelastic nature of the material?
A. You'll certainly get more accurate results if you model the material as it is, which is the superelastic response.
Q. We've talked about the difference in your analysis relating to the tissue of the -- in the IVC and surrounding the IVC and the distant -- difference in your analysis of Nitinol and the superelastic properties of Nitinol.

Are there also differences between your analysis and Dr. McMeeking's analysis relating to filter -- the actual filter geometry itself?
A. Sure. So as I mentioned, Dr. McMeeking just had that portion of the filter, just a portion of a single arm, whereas our analysis had the entire filter with all six arms and all six legs.
Q. And does the filter impact, once it's implanted in the IVC,

does it impact movement of the IVC?
A. Correct, it does. And -- well, it depends on the diameter of the IVC. And so the filter, when you -- you crimp it down onto the catheter and then it springs back, and so it deploys out. And so it's putting a force on the IVC. It's pushing against the walls of the IVC.

And so that force will -- depending on the situation, may influence the motion of the IVC. And that's why, by modeling the complete environment of the filter and the IVC, we're able to capture when that happens and when that doesn't very naturally.

Q. And did you, again, prepare another demonstrative that explains this?

A. Yes.

MS. HELM: May we see 7816, please?

BY MS. HELM:

Q. And, Dr. McMeeking, is this the demonstrative that explains -- I apologize. I'm calling everyone the wrong name and can't even get the right profession sometimes.

Dr. Briant, is this the demonstrative that explains what you were just discussing?

A. Yes, it is.

MS. HELM: Your Honor, at this time I'd like to publish 7816 as a demonstrative.

MR. O'CONNOR: No objection.

THE COURT: You may.

BY MS. HELM:

Q. Dr. Briant, would you explain in 7816, on the left-hand side where it says G2 Filter in IVC With Surrounding Tissue, would you explain to the jury what that depicts?

A. Sure. So this is the output from our analysis. So we were doing these analyses with a computer using finite element analysis, as we talked about. So we have the filter geometry. We have the surrounding tissue, as we saw earlier.

And so this is the resulting output. So on the left what we're looking at is the deformed shape of the filter. And so we have two images. We looked at various cases, but this shows two of them.

On the far left is the not perforated case. And what I'll call your attention to is you can see where the arms contact the filter -- or contact the IVC, how the IVC has been bulged out. And that's due to the forces from the filter acting on the IVC.

We also looked at perforated cases, where we allowed the filter to fully perforate. And, again, you can see a similar situation where it's bulged out on the right-hand side of those images.

Q. And on the right-hand side, where it says "perforated," how much perforation did you use in your calculations?

A. So we modeled it as fully perforated, where it's basically

gone back to its original shape.

Q. And would you tell us what 7816 depicts on the right-hand side, where it says Comparison of Calculated Strains for Perforated G2 Filter?

A. Sure. So what this is showing is a comparison of the strains you would get using Dr. McMeeking's calculations compared to our analysis.

So we have three different cases that are plotted here. Again, we looked at more than this, but this is three different cases where we have different amounts of motion that we're applying. And then we have the strain on the Y axis, the vertical axis, which is, again, how much strain the device has seen or how much deformation it's got.

And so the red bars are the results using Dr. McMeeking's assumptions and his calculations, compared to the blue bars where we have the entire filter and the surrounding soft tissues and model the whole thing.

Q. Are you saying that the assumptions made by Dr. McMeeking had a large influence on his results?

A. Yes. And you can see that by the difference --

THE COURT: Hold on, please.

MR. O'CONNOR: Objection. Leading.

THE COURT: If you stand, Mr. O'Connor --

Mr. Briant, if he stands, hold off on your answer.

THE WITNESS: My apologies.

THE COURT: Sustained as leading.

BY MS. HELM:

Q. Dr. Briant, do you have an opinion as to whether Dr. McMeeking's assumptions had an influence on the results he obtained?

A. Yes. And you can see --

Q. Would you explain that opinion, please?

A. Sure. And you can see that by the difference in the red bars versus the blue bars in that plot, where if you had the rigid IVC and constrained rotation, then you get much higher strains than would actually occur if you have the filter in its surrounding environment.

Q. Did Dr. McMeeking make any other assumptions about the Nitinol wire that Bard used in its filters?

A. Yes, he did.

Q. And did he make any assumptions relating to the fatigue strength of those wires?

A. Yes, he did.

Q. And what were those assumptions?

A. So once we've done these calculations in order to assess the strains and see how severe they are, we compare the strains to what's called the fatigue strength, which is the strength of the material, which is determined from testing.

And so Dr. McMeeking, in order to do this comparison, used data from Nitinol that was from the literature, so not

actually from testing of Bard wire. And he used a value that that was quite low, lower than just about anything I've ever seen, that he pulled from literature.

Q. And what information did you use to evaluate the fatigue strength of the Bard Nitinol wire used in the Bard IVC filters?

A. Sure. So Bard has done testing on their wire and taken it to failure and looked at the strength of the wire, and so that was the value that we used.

Q. Okay. So we've talked about the differences in your opinions relating to the IVC, the Nitinol, the superelastic properties of Nitinol, and the dimensions of the filter itself. And Dr. McMeeking came in earlier in this case and told the jury that he had done analysis and calculations.

A. Correct.

Q. And you've just explained analysis and calculations that you did. Did you do anything beyond analysis and calculations after you did those?

A. Yes. We did laboratory testing on the filters also.

Q. And when you say "laboratory testing," would you explain what you mean?

A. Sure. So that was -- we had actual filters, and we did testing in our lab to verify or validate our calculations to make sure that they were representative of reality.

Q. And did the bench testing -- is laboratory testing sometimes called bench testing?

A. Yes. They're the same, because you do it on a bench.
Q. Did the bench testing you performed validate your calculations and analysis?
A. Yes, it did.
Q. And how?
A. So we compared the results from the bench testing to the forces that we see from the calculations, and we saw good agreement.
Q. And did you prepare a demonstrative to show the bench testing and the comparison that you received?
A. Yes, I did.
MS. HELM: Could we pull up 7815, please.
BY MS. HELM:
Q. And, Dr. McMeeking, is this the document -- I give up.
Dr. Briant, is this the document you prepared to show the bench testing comparison to your calculations?
A. Yes, it is.
MS. HELM: Your Honor, at this time I tender 7815 for demonstrative purposes.
MR. O'CONNOR: No objection.
THE COURT: You may display it.
BY MS. HELM:
Q. Dr. Briant, would you explain to the jury what this slide shows.
A. Sure. So this shows the testing that we did for the strain

analyses as well as the results.

Q. Okay. And on the left is a picture. And is that -- what does that picture depict?

A. Sure. So on the left-hand side we see the test setup. And what you can see there is one of the filters that we have for the testing, and that is a G2 filter. We did testing on both G2 and Recovery.

And so what happens during the tests is we hold the filter, as you can see, and then we have this rod that comes down vertically from the top. And this is done on what we call an Instron machine.

And so that rod comes down and it pushes on arms -- on an arm or leg. We tested both. And then it measures the force that's required to push down on that arm.

Q. And on the right-hand side, there's another graph. Can you explain what that graph depicts?

A. Sure. So this is the result from the test, so this is the output from the Instron machine.

And on the horizontal axis we have displacement, so that's how much the rod has traveled. And on the vertical axis we have force, so it's how much force it took to do that.

And so the results from the tests, from the experiments, are those solid lines that you can see there. There's two of them. And then the black dashed line, that's the result from the analysis.

And as you can see, we got good agreement between our calculation results, what was predicted by the analysis, as well as the experimental testing.

Q. And on the graph, on the right-hand side of 7815, it says -- when you talk about analysis, it says "FEA." Is that finite element analysis?

A. Correct. Yes.

Q. And could you, as simply as possible, and I know it's not simple, explain to the jury again what finite element analysis means?

A. Sure. So finite element analysis is an analysis technique to do these strain calculations. And it's a technique that we use when the situation that you're trying to calculate is too hard to do by hand. It allows us to do the calculations with a computer.

Q. And did you do anything else other than -- in addition to the bench testing, did you do anything else to verify the accuracy of your calculations that you performed through finite element analysis?

A. So we did comparisons to literature. And the main thing I'm talking about there, as I mentioned, is studies have looked at patients that have filters in them. And as I mentioned, the diameters of the IVCs that they measure with the filters at the filter location is larger than above or below the filter. And again, this just verifies that the filter -- the IVC is

responding to the presence of the filter and the forces that the filter puts on it.

Q. Based on the calculations and analysis and the testing and analysis of your testing, do you have an opinion as to whether the strains that Dr. McMeeking calculated were accurate?

A. I think that they were inaccurate, for all the simplifications and assumptions that we've talked about.

Q. And is that opinion held to a reasonable degree of engineering certainty?

A. Yes, it is.

Q. Okay. I want to switch briefly and talk to you very briefly about tilt.

We've talked about the fact that Ms. Hyde only had a 2- to 4-degree tilt in her filter. But did Dr. McMeeking also do some analysis relative to tilt?

A. Yes, he did.

Q. And what was it -- very briefly, what did Dr. McMeeking do?

A. So he, again, did analytical hand calculations as well as finite element analysis related to tilt.

Q. And what did Dr. McMeeking conclude about tilt in Bard retrievable IVC filters?

A. So he concluded that the filters were likely to tilt, all the types of the filters.

Q. And are you critical of the assumptions that Dr. McMeeking used in his calculations and analysis relating to tilt?

A. Yes, I am.
Q. And why are you critical of it?
A. So Dr. McMeeking, in his calculations, assumed three things, all of which would resist tilting.

Number one, he assumed that the friction -- there was no friction between the IVC and the filter, so -- and we know that friction would happen. Friction would be present between the IVC and the filter. And he didn't include that in his analysis.

Number two was he again looked -- assumed that the IVC was rigid as opposed to deformable. And as you saw in those previous images how the filter will cause the IVC to tent and deform, and that will resist tilting further.

And then lastly, he didn't include the hooks on the legs that would have to -- that would also resist tilting.
Q. And did you do your own analysis of the propensity of Bard filters to tilt?
A. Yes, we did.
Q. Okay. And can you explain to us briefly what you did in your analysis of tilting?
A. Sure. So we used the same basic setup that we did for our strain calculations. We had our filter, and we deployed it into the IVC. But this time, rather than pulsing it, we pushed on the cap, on the top, and looked at the amount of force that it took to tilt the filter over.

Q. And did Dr. McMeeking express any opinions about the impact of tilt on other filter complications?
A. Yes, he did.
Q. Do you agree with those opinions?
A. No, I don't.
Q. Why not?
A. So Dr. McMeeking was of the opinion that tilt would increase the likelihood for other complications such as perforation and fracture.
Q. And did his analysis permit one to make that scientific conclusion?
A. No, it did not.
Q. And why not?
A. So we did our own calculations to look at this. And in regard to perforation, what we did was we looked at filters -- the forces from filters in different diameters of the IVC, so in large IVCs and small IVCs.

And what we found was that the force obviously increases as you decrease the diameter of the IVC. And those increases in forces are well beyond what you get when you just tilt the filter over, yet there's no indication in the literature that, like, smaller IVCs are more prevalent to perforation than larger ones or anything like that.

In addition, we looked at the interrelationship between tilt and strain or fracture and found that -- we,

again, looked at -- analyzed tilted filters and actually found very similar or slightly lower strains in tilted filters than in straight ones.

Q. And are the opinions that you are offering today about Dr. McMeeking's analysis of tilt and the opinions you're offering about your analysis of tilt, are those being offered to a reasonable degree of engineering certainty?

A. Yes, they are.

Q. I want to switch gears and talk to you about some testing.

Dr. -- your second opinion that you told the jury about was that Dr. McMeeking criticized Bard's testing of the filter in the development process.

A. Correct.

Q. Okay. Did you review his analysis of Bard's testing?

A. Yes, I did.

Q. And what is your understanding of Dr. McMeeking's criticism of the testing Bard did for the G2, G2X, and Eclipse filters?

A. That he was critical of it and thought it was inadequate.

Q. Did you look at Bard's testing?

A. I did, yes.

Q. Do you do testing?

A. I do, yes.

Q. Other than the testing to confirm your analysis on strain and tilt that we've just talked about, were you asked to do any other testing in this case?

A. The testing that we did was just to validate our calculations.
Q. Okay. But based on the review of -- and, again, remind the jury what you had available to you relating to Bard's testing.
A. We had the testing documents.
Q. Okay. And based on your review of the testing documents and your experience, do you have an opinion about Bard's testing for the G2, G2X, and Eclipse filters?
A. Yes. My opinion was that the testing that Bard did considered all the relevant complications that are known to occur with IVC filters.
Q. And in addition to calling you the wrong name and stumbling over words, I also left off a filter, so let me ask it again.

Do you have an opinion about the testing that Bard did for the Recovery, the G2, the G2X, and the Eclipse filters? Is it the same opinion?
A. Yes, it would be the same. The testing considered all the relevant complications.
Q. Did Bard take into consideration the superelastic nature of Nitinol in its testing?

MR. O'CONNOR: Objection. Nondisclosure.

THE COURT: Ms. Helm?

MS. HELM: April 2017 report, page 51, Section 10.

THE COURT: And where on that page?

MS. HELM: Section 10, in the first full paragraph, in

the second line, "Including the use of superelastic."

THE COURT: Okay.

Objection is overruled.

BY MS. HELM:

Q. Dr. Briant, do you remember the question?

A. Yes, I do.

Q. Do you mind --

A. Sure, yeah. So Bard included the superelastic effects in their analyses.

Q. Did Dr. McMeeking also have a criticism of whether Bard took into account pulsation in its testing?

A. Yes, he did.

Q. And what was your -- did Bard take that into consideration?

A. Bard looked at the effects of pulsation, yes.

Q. Has Dr. McMeeking offered any alternative or any testing that Bard should have done?

A. He has made suggestions.

Q. Are those suggestions, suggestions that you can analyze to a reasonable degree of engineering certainty?

A. No, because he hasn't provided anything to analyze.

Q. And to be able to analyze a test, what would you need to know?

A. So you would need design drawings, you know, analysis testing in order to be able to assess whether an alternative design might work.

Q. Okay. We've talked about the differences between your assumptions and calculations. We've talked about your analysis of Bard's testing.

Dr. McMeeking was here, and he said that Bard did not test to worst case scenario. Are you familiar with his opinion on that?

A. Yes, I am.

Q. Okay. And why did Dr. -- so do Dr. McMeeking's assumptions that he made, why don't they represent worst case scenario?

A. Sure. So as we talked about, Dr. McMeeking made assumptions such as the infinitely stiff IVC that are beyond what the human body can do. So his assumptions weren't a reasonable worst case that actually could be experienced by the filter but beyond a physically possible worst case.

Q. And Dr. -- if Dr. McMeeking were to criticize your assumptions as being favorable to filter performance, would you agree with that?

A. No. Definitely not. We used conservative values based on the literature in a lot of different locations. We also looked at analyzing the motion of the filter and the strains from three different ways, three different loading modes, in order to try and bound the problem and understand the range of strains that the filter could undergo.

Q. Okay. And did you make those analyses and those conclusions independent of any work done by Bard?

A. Yes. That was all ours.
Q. I want to shift gears with you to your third major opinion, and that relates to the Simon Nitinol filter.
And over the last couple of weeks, the jury's heard a lot about the Simon Nitinol filter. Would you please tell them again what your opinion is in this case as it relates to the Simon Nitinol filter.
A. Yes. It's that, from an engineering perspective, that the Simon Nitinol filter is not an alternative design or alternative product. And that's because it lacks the retrievability. It lacks that functionality which the Bard G2 filters have.
Q. What analysis would be required from an engineering perspective to determine scientifically if there was an alternative safer product to the one you already have?
A. Sure. So that would be what I talked about. You'd have to start with creating a design, design drawings, and then going through analyses and testing in order to be able to verify that your design is viable and that it would actually work.
Q. And have you heard the term "unintended consequences"?
A. Yes, I have.
Q. And what does that mean from an engineering perspective?
MR. O'CONNOR: Objection. Nondisclosure.
MS. HELM: Your Honor, may I reask the question so that I can confirm the disclosure?

THE COURT: Reask it, please.

BY MS. HELM:

Q. What do you mean -- I used the term "unintended consequences." I'm going to switch it.

What do you mean when we talk about consequences of a change to a design?

A. So when you change a design, you could -- while you may be trying to help one complication that's occurring, it could exacerbate other complications.

Q. And, Dr. Briant, I have just a couple questions -- well, let me back up.

Has any analysis been done by Dr. McMeeking to determine what would be necessary to make the Simon Nitinol filter a retrievable filter?

A. No, he hasn't.

Q. And I want to switch gears with you just a little bit more.

The jury has heard in this case that as of March of 2011, when Ms. Hyde got her filter, that Bard was working on some other projects and some other filters, and that subsequently Bard had filters on the market called the Meridian and the Denali.

As part of your work in this case, were you -- did you see any opinions by Dr. McMeeking relating to the Meridian and the Denali filters?

A. Yes, I did.

Q. And would you tell the jury, please, what Dr. McMeeking's opinions are about the Meridian and the Denali filters.

MR. O'CONNOR: This is not in this expert's report.

THE COURT: Ms. Helm?

MS. HELM: Your Honor, it's in his May 2017 report, page 23. In fact, that entire report addresses those two filters, Your Honor.

THE COURT: Where on page 23?

MS. HELM: Paragraph 5.2.1.

THE COURT: Objection is overruled if the criticism you're going to have him describe is 5.2.1.

BY MS. HELM:

Q. Dr. Briant, did Dr. McMeeking offer an opinion that the design process of the Meridian and the Denali filters was not valid?

A. Yes. That's what he thought.

Q. And did he offer an opinion that the Meridian and the Denali filters, from his point of view, would suffer from the same complications as the previous generations of Bard filters?

A. Yes. That was his opinion.

Q. And did he offer an opinion in his report that those filters would experience tilt, perforation, migration, and fracture?

A. Yes, he did.

Q. Have you had an opportunity to review Dr. McMeeking's

testimony in this case?
A. Yes, I have.
Q. Did he offer that opinion -- did he tell the jury that when he was here?
A. Not that I recall.
Q. Okay. When Dr. McMeeking was here, he testified that he had the concept of a filter that had caudal anchors, penetration limiters, and a change in the angle of the wires coming out of the cap.
Did you read that testimony?
A. Yes, I did.
Q. Have you analyzed this idea that Dr. McMeeking has for this changed filter?
A. No, I have not.
Q. Why not?
A. Again, because there's been nothing to analyze. Nothing's been proposed.
Q. In order to determine whether changes to caudal anchors, penetration limiters, and the angle coming out of the wire, whether a filter with those changes would work, what would you need to do?
A. Again, that would be, you know, coming up with a design, actually doing engineering analysis on it, and testing it, again, to see if your design is viable and if it would work.
Q. If you don't come up with a design, you don't analyze it,

you don't build a prototype, and you don't test it, from an engineering perspective, what do you have?

MR. O'CONNOR: Objection. Leading and nondisclosure.

THE COURT: How do you respond on nondisclosure, Ms. Helm?

MS. HELM: Your Honor, on his July 2017 report, on page -- well, page 7, Section 5.0, paragraph 3, lines 6 to 11.

MR. O'CONNOR: I'm not aware of the July report for this. Hang on. I'm sorry, what page?

MS. HELM: 7, Section 5, paragraph 3, lines 6 to 11.

THE COURT: There's four paragraphs on that page. I'm assuming you mean paragraph 4, since paragraph 3 doesn't have 11 lines.

MS. HELM: The opinion -- I numbered the paragraphs. It's the last paragraph.

THE COURT: Okay.

I think all he does is state what Dr. McMeeking does not do. He doesn't state what the effect would be, so the objection is sustained.

BY MS. HELM:

Q. Dr. Briant, within a reasonable degree of medical certainty, do you have what you need to analyze Dr. McMeeking's idea about changes to an IVC filter?

A. From an engineering perspective, no.

MS. HELM: No further questions at this time.

THE COURT: All right. Cross-examination.

CROSS-EXAMINATION

BY MR. O'CONNOR:

Q. Dr. Briant, how are you?

A. Good. How are you?

Q. Good. I'm impressed with a B in Greek Mythology.

Dr. Briant, I just want to go back to something about what Exponent has made in this case. It's been paid $700,000; right?

A. Approximately, yes.

Q. And that has been for activities by you and engineers to defend Bard in this case; right?

A. It's been to do the analysis that was requested of us.

Q. Which includes defending Bard; right?

A. It's to analyze Dr. McMeeking's analysis.

Q. So for $700,000, your firm, with other Ph.D. engineers just like you, have been paid for the limited purpose of criticizing Dr. McMeeking; is that fair?

A. Yes. My role in this case has been to analyze and assess the opinions of Dr. McMeeking and the calculations that went into those opinions.

Q. Thank you.

And you did testing to verify your own calculations; correct?

A. That's correct.

Q. You and your other engineers did nothing to verify or validate testing that was done at Bard; correct?
A. Correct. Our work was for our own calculations.
Q. And let me ask you this, Dr. Briant: You, at Exponent, your firm does things like root cause analysis; correct?
A. Yes, we do.
Q. And you're certainly capable to be retained by Bard to do a root cause analysis of its filters and filter problems that you've become aware of; correct?
A. That's something we could have looked at.
Q. And Bard has never asked you to do that; correct?
A. That's correct.
Q. And what you do know is that Bard filters, including the G2, the G2X, and the Eclipse, have tilted; right?
A. I'm aware that tilting occurs, yes.
Q. You're aware that Bard filters have perforated; correct?
A. I'm aware of that, yes.
Q. You're aware that they have perforated through the vena cava walls; correct?
A. I'm aware that can occur, yes.
Q. And you're also aware that Bard filters fracture, break, and embolize to other parts of the body; correct?
A. I'm aware that can occur, yes.
Q. What you haven't seen is internal information from Bard and what Bard knows about the rate that occurs; true?

A. I've seen one table about complication rates. But other than that, no.
Q. And what Dr. McMeeking did is he took out calculations and he -- for his analysis and his assumptions, he assumed the worst case scenario. You agree with that?
A. It's my opinion that he assumed -- incorporated assumptions into his analysis that were beyond what -- the physical worst case.
Q. I'm just breaking it down.

He testified and wrote in his report that he assumed the worst case scenario. You agree with that?
A. That's what he wrote. That's correct.
Q. And he assumed that Bard IVC filters have been known to tilt; correct?
A. He wrote that, yes.
Q. He assumed that Bard filters have perforated the vena cava walls; correct?
A. Yes.
Q. He assumed Bard filters have perforated and fractured; correct?
A. Yes.
Q. And he assumed that filter arms will sometimes get stuck -- what do you call that -- endothelialized into the wall of the vena cava; correct?
A. He talked about that, yes.

Q. And you know that all those things have happened to Bard filters; correct?
A. I'm aware those can occur, yes.
Q. And one reason that a medical device company should do testing and analysis and calculations is to help predict what will happen when a device is in the real world; correct?
A. Right. Medical device companies are looking to evaluate and understand how their devices will perform, yes.
Q. You agree that's an absolute obligation they have, to understand as best they can what's going to happen once that filter is placed in human beings; true?
A. Yes. I think medical device companies should evaluate the environments that their devices are going to be put into and look at it.
Q. And Bard filters have migrated, tilted, fractured, embolized, and perforated; right? We know that's happened in the real world; correct?
A. Yes. I'm aware those occurred.
Q. And Dr. McMeeking's calculations have shown that the filters tilt under certain circumstances; correct?
A. He shows they can tilt, yes.
Q. Dr. McMeeking, through his finite element analysis and calculations, has showed that Bard filters migrate under certain circumstances; true?
A. I don't believe he looked at migration.

Q. Okay. Well, you've -- we could check his report, both of us, couldn't we?
A. We could, yeah.
Q. You know that Dr. McMeeking's calculations have shown that Bard filters perforate and fracture; correct?
A. He talks about those in his report, yes.
Q. And those were consistent with what he testified were the result of his calculations; true?
A. Under the analysis assumptions that he did and incorporated, yes.
Q. And, in fact, those failure modes, we all know, have occurred in the real world; true?
A. Yes. Those can occur.
Q. The disagreements, when it comes right down to it, between you and Dr. McMeeking are how stiff the tissue surrounding the IVC is -- that's one area that you disagree; true?
A. That's one of them, yes.
Q. All right. And another is how tightly the IVC can hold on to an arm when it is perforated or endothelialized; correct?
A. Yes. Dr. McMeeking assumed that there couldn't be any rotation where the filter contacted the arm.
Q. And another area of disagreement between you and Dr. McMeeking is how the filter responds to stresses and strains; correct?
A. Well, so both of us are calculating the stresses and

strains inside the filter under these different conditions.
Q. His stresses and strains that he assumed in his calculations led to perforation, tilt, and fracture; right?
A. The calculations that he did suggest that, under his assumptions, that fracture would occur.
Q. Now, when you were retained in this case and you wrote your case-specific report, you said that Lisa Hyde had a G2X filter; correct?
A. Yes, that's correct.
Q. You were clear and unequivocal about that; right?
A. Yes. That was based on the information I had at the time.
Q. And nobody from Bard ever asked you to correct that; true?
A. Correct the report? No.
Q. And you know that Lisa Hyde's filter, among other things, perforated through the vena cava wall; correct?
A. That's my understanding, yes.
Q. And you're aware of that happening to other patients. You've reviewed literature and have seen it happen and are aware of that happening in Bard filters in other patients; correct?
A. Yes. Perforations can occur.
Q. And you're aware that her IVC filter perforated into or above it or interacted with her aorta; correct?
A. Yes. That's correct.
Q. Okay. And you know that another filter leg interacted with

her vertebrae at L3; correct?
A. I'd have to go back and review that detail.
Q. Any reason to disagree with that?
A. No. I don't have any reason.
Q. And you know from your work in -- with Bard that those things have happened to Bard filters; correct?
A. Yes. I'm aware that happens.
Q. And you also know that her filter arm perforated through the vena cava, broke, and traveled to her heart and it required a surgery. You know that; correct?
A. Yes, I'm aware.
Q. And you know that has happened to other Bard filters; correct?
A. Yes, I'm aware.
Q. And Dr. McMeeking explained through his calculations, through his finite element analysis, why that happens; true?
A. Under the assumptions that he used in his calculations, he determined high strains that would suggest fracture.
Q. Well, if you assume a filter's fracture and you can prove it, there's something good about that test; right?
A. That would depend on the assumptions that are used.
Q. But, in fact, his assumptions and his calculations showed tilt, perforation, fracture, and embolization; right?
A. His calculations show that fractures could occur under his assumptions and that tilt could occur, again, under his

assumptions.
Q. You do agree that a medical device company must always put patient safety first; correct?
A. Yes, that should be first.
Q. And a medical device company should do everything it can to understand the environment where a device is going to be used. You agree with that; correct?
A. I think that companies should look at the environment of the device, yes.
Q. And when it comes to IVC filters, a medical device company like Bard should, under all circumstances, understand the dynamics of the vena cava; right?
A. I think they should try to understand it to the best of their abilities.
MR. O'CONNOR: Thank you.
THE COURT: Redirect?

REDIRECT EXAMINATION

BY MS. HELM:
Q. Dr. Briant, are you aware of whether all IVC filters can fracture?
A. Can they fracture?
MR. O'CONNOR: Objection. Nondisclosure.
THE COURT: Overruled. It's fair redirect.
THE WITNESS: I'm sorry. Can you repeat the question?

BY MS. HELM:
Q. Can all IVC filters fracture?
A. They could. My understanding is that they don't.
Q. Okay. Not every filter fractures?
A. Correct. That's my understanding.
Q. But let me -- we got a little discombobulated there. Let me back up.

Are you aware of instances of filters manufactured by companies other than Bard that have suffered fractures?
A. I'm aware of them, yes.
Q. And are you aware of instances where filters manufactured by companies other than Bard have suffered from tilt, perforation, and migration?
A. I'm aware of those, yes.
Q. Those are complications of IVC filters -- are those complications of IVC filters?

MR. O'CONNOR: Objection. Leading and nondisclosure.

THE COURT: Overruled.

THE WITNESS: Yes, those are known complications of IVC filters.

BY MS. HELM:
Q. Thank you.

Okay. And Mr. O'Connor stood up here and asked you about all the calculations and Dr. McMeeking's calculations assumed this and did this and did that.

In your opinion, to a reasonable degree of engineering certainty, did Dr. McMeeking's assumptions and calculations accurately depict what can happen to an IVC filter in the human body?

A. No, because he assumed things that we know were beyond physical limits. For example, we know the IVC is not infinitely stiff.

MS. HELM: Thank you. No further questions.

THE COURT: All right. Thank you, sir. You can step down.

THE WITNESS: Thank you.

(Witness excused.)

MS. HELM: Your Honor, at this time we call John Van Vleet.

THE COURT: If you want to stand up, ladies and gentlemen, while he's coming in, you may.

Mr. Van Vleet, you can come directly back to the witness stand. You're still under oath for purposes of this trial.

JOHN VAN VLEET,

called as a witness herein by the defendants, having been previously duly sworn or affirmed, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. HELM:

Q. Good afternoon, Mr. Van Vleet.

A. Good afternoon.

Q. Would you please reintroduce yourself to the jury, remind them who you are.

A. Sure. My name is John Van Vleet. I was the vice president of regulatory affairs and clinical programs for Bard Peripheral Vascular from June of 2007 until December of 2017.

Q. Thank you.

When you joined Bard in 2007, did you have previous experience in regulatory affairs for a medical device company?

A. Yes.

Q. And did you have an approach that you had developed over the years in working in regulatory affairs for a medical device company?

A. Yes. It was what I would call a collaborative approach with regulators, whenever possible, with the FDA.

Q. And when you arrived at Bard, did you see your approach relating to regulatory affairs already in action at Bard?

A. Yes, I did.

Q. And what did you do? How did you address that?

A. I built on it. It was a very organized and formalized program, good documentation practices, good, thorough communication. Anytime there were telephone conversations with

FDA, an email was generated to document that, and these all went into the regulatory files.

Q. I injected, and I think the jury probably remembers, that you said you were vice president of regulatory affairs and clinical programs for Bard. Would you just briefly explain what your responsibilities were in that role?

A. So I was responsible for overseeing the interactions between Bard, my division of Bard, and any regulatory body, whether it was in this country or in any other country. The Ministry of Health equivalent in the United States is the Food and Drug Administration.

On the clinical side, many of our products required certain levels of evidence to be submitted with applications to regulatory bodies, to Ministries of Health. And so we would design studies in collaboration with the FDA, most of the time, and other Ministries of Health globally. And then another team would be the operational team that would actually conduct these clinical trials across medical centers in United States and actually globally as well.

Q. During the ten years that you were with Bard, did you have responsibility for products other than IVC filters? We're assuming IVC filters because you're here today.

A. Yes. Yes.

Q. Would you just briefly explain what other products you were responsible for.

A. Sure. So this division of Bard serves the end stage renal disease community, specifically, patients that are dialyzing; they serve people that are being biopsied for different types of cancer, mostly breast cancer; they serve peripheral arterial disease patients, so a lot of balloon angioplasty and self-expanding stents and drug-coated balloons; and then vascular surgery products, in addition to the filter which is for treating thromboembolic disease, but we also made artificial grafts to enable people to do surgeries to bypass.
Q. Okay. And during this time period that you were at Bard and responsible for regulatory affairs, explain the level and amount of interaction you had with the FDA.
A. We had weekly, at minimum, contact with FDA. If you think about the family and breadth of products and the different groups and reviewers at FDA, we would at least have a once-a-week contact with them. That could be in the way of a face-to-face meeting, it could be a phone conference, it could be an email exchange, or just a simple one-on-one phone call.
Q. Did you have conversations with FDA about Bard's IVC filters?
A. Yes.
Q. Often?
A. Often.
Q. Let's back up. I don't think the jury, the last time you were here, the jury got to know you.

Where did you grow up?
A. I was born and raised in the Dominican Republic, about 40 miles from Haiti. My parents were missionaries there from 1941 to 1980.
Came to the States to go to university and went to Purdue and kind of fell into Indiana and the orthopedic business there for about 20 years.
Q. And what degree did you receive from Purdue?
A. A Bachelor of Science in biology with a minor in chemistry.
Q. And after you graduated from Purdue, did you obtain any other postgraduate education?
A. Yeah, I was accepted into a medical technology internship program for 12 months and then finished by taking my boards by -- with the -- by the American Society of Clinical Pathologists. Still retain that license. I've never really practiced but -- other than volunteer health clinics.
And then years and years later, when I was no longer working kind of on the bench or in a front-line capacity, I was doing things that I didn't have business training for, so I went back to get an MBA from Marian College.
Q. And where do you live now?
A. I live in Tempe.
Q. And how long have you lived in the Phoenix area?
A. Since June of 2007.
Q. And I believe when you were here previously, you told the

jury that you left Bard at the end of last year. Are you employed?
A. Yes.
Q. And what are you doing today?
A. I'm vice president of clinical affairs and regulatory programs, almost exact opposite but the same, for a company called Corindus Vascular Robotics. It's an intravascular robotics company based in Waltham, Massachusetts.
Q. And do you have the privilege of being able to work from Phoenix rather than Massachusetts?
A. I have the privilege of being able to work from my office in Tempe. Thank you.
Q. Phoenix feels a little bit like the East Coast today.
A. Yes.
Q. And would you just remind the jury how many years you've been in the medical device industry.
A. 30 years.
Q. Why have you decided to devote your career to the field of medical devices?
A. Through my undergraduate, I worked in a hospital environment that actually had tuition reimbursement, and I really enjoyed the interaction and the contact with patients and that aspect of it. But I learned that with a family and more expenses, that I -- that there were other opportunities to work in a medical environment but still be able to have that

same level of satisfaction of working clinically with patients and seeing patients benefit from the type of work that you do and the products that you help to create.

Q. And what was your first opportunity to enter the medical device industry?

A. I was in the MBA program, and I was being interviewed by a team. And after they heard about my background working in the hospital -- and at that point in time I was working for a hazardous waste landfill as their chief chemist and lab manager.

She wanted to know why I was working for a hazardous waste company and not working for her, and I determined later she was the director of human resources for Bristol-Myers Squibb's orthopedic company, Zimmer, at that time. And literally two and a half weeks later, I stumbled into this career.

Q. Great. Okay. Let's fast-forward your career a little bit, and let's come to the time when you started at Bard.

And when you started at Bard, did you start -- when you got in, did you start, as part of your responsibility, having responsibility for the regulatory and clinical affairs for Bard's retrievable IVC filters?

A. Yes.

Q. And at the time that you arrived at Bard -- and we're going to -- the jury's heard a lot of history in bits and pieces, and

I'm going to try to see if we can put it in time.

The EVEREST clinical trial was -- had just been completed?

A. Correct.

Q. Okay. And would you remind the jury just very briefly what the EVEREST clinical trial was.

A. It was a 100-patient multi-center trial that was designed to evaluate the safety of retrieval of the G2 filter system.

Q. So when you arrived at Bard, was the G2 filter available for use as a permanent filter?

A. Yes.

Q. And when you arrived at Bard, had the clinical trial just been completed to evaluate that filter to be available as a retrievable filter?

A. Yes.

Q. And were you at Bard for the G2X and the Eclipse as well?

A. Yes.

Q. Okay.

A. Correct.

Q. Before we go into the clinical study and the -- and EVEREST and bring ourselves forward in time, I have a couple questions to ask you.

In your 30 years of working with medical devices, are there any implantable medical devices of which you are aware that do not carry the risk of complications?

A. Not that I'm aware of.
Q. Okay. So when you got to Bard, the clinical trial, the EVEREST clinical trial had been completed. And let's put a date on that, just so that we have our timeline in place. When was that?
A. Sure. So I arrived -- June 4th was actually my first day. I believe the last follow-up in the trial had been completed in May or April of that month. And the clinical study report had already been drafted when I started.
Q. Okay. So this is June of 2007?
A. Yes.
Q. Okay. And when you arrived at Bard, did you go back and study and determine what had taken place relating to the regulatory and clinical work on the Bard G2 filter?
A. Yes.
Q. Did you review the EVEREST clinical study related files?
A. Yes.
Q. And once you started with Bard, did Bard have to provide information and updates to the FDA relating to the EVEREST clinical study?
A. Yes. As soon as the study is approved by the FDA to be conducted, every six months we're required to prepare reports to the FDA notating enrollment, which investigational sites are currently enrolling, and then a summary of all complaints and adverse events collected.

Q. Thank you.

MS. HELM: Would you pull up 5333, please.

Your Honor, this is -- I believe this is in evidence. May I publish?

THE COURT: You may.

BY MS. HELM:

Q. Mr. Van Vleet, can you tell the jury what 5333 is, please?

A. Sure. It is one of the -- as I mentioned before, required annual IDE progress reports. I believe this was the one that would be more comprehensive and including adverse events.

Q. And this report was actually prepared before you arrived at Bard, wasn't it?

A. It was.

Q. Okay. And the jury heard about this from Ms. O'Quinn yesterday.

So when you arrived at Bard in June, did the responsibility for these reports become yours?

A. Yes.

MS. HELM: You can take that down, please.

BY MS. HELM:

Q. And the next report is due six months later?

A. Yes.

Q. Okay. So that would be approximately August of 2007?

A. Yep. Yes.

Q. And were you responsible for the August 2007 report to FDA

relating to the EVEREST study?
A. Yes.
MS. HELM: Scott, could we pull up 5335, please.
BY MS. HELM:
Q. And, Mr. Van Vleet, can you see that?
A. Yes, I can.
Q. Is that an August 2007 report prepared by Bard to the FDA relating to the EVEREST study?
A. Yes.
Q. And was this report prepared either by you or at your direction?
A. Yes.
MS. HELM: Your Honor, at this time I would move to admit 5335, if it's not already in evidence. I would move to admit 5335.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 5335 admitted into evidence.)
MS. HELM: May I publish, Your Honor?
THE COURT: You may.
MS. HELM: And may we go to page 18, please. At the bottom of the page, the last paragraph.
BY MS. HELM:
Q. Mr. Van Vleet, did Bard tell the FDA about complications that occurred with the G2 filters during the EVEREST study?

A. Yes.
Q. And what information did Bard provide to the FDA?
A. All the information surrounding all adverse events observed in the clinical trial.
Q. And here, in the highlighted section, what did Bard -- was Bard telling the FDA about reports of migration that occurred during the EVEREST study?
A. Yes. It was talking about 10 filter migrations greater than 2 centimeters reported with a mean follow-up of five months. It identified them as being downward, or caudal in direction, between 2.0 and 4.1 centimeters, and without any clinical sequelae or complications.
Q. And it doesn't say without complications. It says without clinical sequelae. And does that mean without complications or symptoms?
A. That means without any resulting clinical observations as a result of the event.
MS. HELM: You can take that down, Scott.
BY MS. HELM:
Q. In response to reports on the -- such as this on the EVEREST study, did Bard get questions or responses from the FDA?
A. We did.
Q. In other words, you didn't just send a report in and then radio silence?

A. No.

MS. HELM: Would you pull up 5334, please.

BY MS. HELM:

Q. And, Mr. Van Vleet, can you see that?

A. Yes.

Q. And can you tell me what that is, please?

A. That is a letter to the Bard regulatory correspondent, Mr. Michael Ryan, from the FDA in response to their review of the annual IDE report. And it has a series of -- first page and like probably has two or three-page letter, and it has a series of questions.

MS. HELM: Your Honor, at this time I tender 5334.

MR. O'CONNOR: Can we scroll through it, Your Honor? Can I see the second page, please?

No objection.

THE COURT: Admitted.

(Exhibit No. 5334 admitted into evidence.)

MS. HELM: Publish, Your Honor?

THE COURT: Yes.

MS. HELM: And would you please turn to page 2. And Scott, could you highlight question -- the paragraph No. 3, please?

BY MS. HELM:

Q. And, Mr. Van Vleet, what did the FDA ask about migration in the report of migration that you had made in August of 2007?

A. They stated that based on the 10 migrations and 100-patient study, that would be equal to approximately a 10 percent rate. They wanted to know why that rate of device migration would be clinically acceptable, and then they would like to have a comparison of the approximate migration rates of the currently marketed Recovery and G2 filter devices based on our clinical experience as compared to the investigational Recovery filter studied in the EVEREST trial.

Q. And did Bard undertake to put together the information and respond to the FDA?

A. Yes.

MS. HELM: Would you pull up 5336, please.

BY MS. HELM:

Q. Mr. Van Vleet, can you identify this document?

A. Yes. This would be our response to the letter from FDA with their questions.

Q. And was this prepared either by you or at your direction as vice president of regulatory and clinical affairs for BPV in October of 2007?

A. Yes.

MS. HELM: Your Honor, at this time I move to admit 5336.

MR. O'CONNOR: May we scroll -- have it scrolled through, Your Honor?

We have no objection.

THE COURT: Admitted.

(Exhibit No. 5336 admitted into evidence.)

MS. HELM: May I publish, Your Honor?

THE COURT: Yes.

MS. HELM: And, Scott, could you go to page 13, please? And would you highlight Question 3 at the bottom of the page, please.

BY MS. HELM:

Q. Mr. Van Vleet, is this Bard's response to FDA's questions about the 10 migrations reported in the EVEREST study?

A. Yes. The text in bold is a direct lift from their letter they sent to us, and then the indented text below would be our response.

Q. And what did Bard tell the FDA in response to the question about the 10 migrations?

A. Sure. So FDA had done the math and calculated a migration rate of 10 percent due to the hundred patients in the study. But actually, in the study, there was only adequate imaging available on 82 patients.

So we revised that percentage, so 10 divided by 82 is 12.2 percent. And then we also, once again, reiterated in this paragraph the distance that they had migrated.

MS. HELM: And can we go on to the next page? And at the top, the first paragraph.

BY MS. HELM:
Q. What else did Bard tell the FDA about those migrations?
A. So we again repeated that in all of the cases of the reported migration, it was in the downward or caudal direction, and the patients were asymptomatic with no clinical sequelae.
Q. And to your knowledge --
MS. HELM: You can take that down, Scott.
BY MS. HELM:
Q. -- were all adverse events, according to the clinical study protocol that occurred in the EVEREST clinical trial for the G2 filter, reported to the FDA?
A. Yes.
Q. And to your knowledge, were all of FDA's questions raised about those adverse events addressed by Bard?
A. Yes.
Q. Okay. Based on the EVEREST study, did Bard ultimately ask the FDA to clear the G2 filter for a retrievable indication?
A. Yes, we did.
MS. HELM: Would you pull up 5340, please.
BY MS. HELM:
Q. Mr. Van Vleet, can you identify this document?
A. Yes. This is the actual application, which would include the clinical study results and our request to have the FDA clear the G2 filter for a retrievable indication.
Q. The jury's heard the term 510(k) as the application

process. Is this the 510(k) application for the G2 as a retrievable indication dated October 31, 2007?

A. Yes.

MS. HELM: Your Honor, my note says this is admitted.

THE COURT: It is.

MS. HELM: May I publish?

THE COURT: You may.

MS. HELM: Thank you.

BY MS. HELM:

Q. Mr. Van Vleet, was this 510(k) application submitted to the FDA before or after the EVEREST study was completed?

A. After.

Q. And does this 510(k) application that was submitted to the FDA include information about the EVEREST study, including the EVEREST protocol?

A. Yes.

Q. The protocol for the study?

A. Yes, it did.

MS. HELM: Can we turn to page -- this is a very thick document, isn't it?

THE WITNESS: It's a thousand-some pages.

MS. HELM: Can we turn to page 263, please.

BY MS. HELM:

Q. And this appears to be like a header of a new section. Would you explain what this section of the 510(k) application

is, please.
A. Sure. This is the actual clinical study protocol that's included -- it's always included as part of the application, and then the clinical study report follows that.
Q. So this is explaining -- is this explaining to the FDA the clinical protocol used for the EVEREST clinical trial?
A. It is. In this case, it's probably more of a technicality because FDA would have already seen that because they would have approved that two years or so before as part of the review process, but it's really helpful to the reviewer when you include it in the application.
Q. Okay. This document, right below the logo, it says Bard Recovery Filter Study (EVEREST).
You see that?
A. Yes.
Q. Why does it say Recovery when it was actually the G2 filter that was being -- for which Bard was submitting a request for retrievability and clearance?
A. Because at the time that that was originally written and submitted to the FDA some two years before, they had -- the marketing team, I guess, had not come up with a different name for the device, and it was called Recovery.
Q. So the Recovery just held over?
A. Correct.
Q. The device was eventually called the G2?

A. G2, yes.
Q. Thank you.
MS. HELM: And could we turn to page 278, please.
BY MS. HELM:
Q. And do you see, on the bottom of 278, it says in paragraph numbered 5, Study Design?
A. Yes.
Q. What is a study design when discussing a clinical study such as the EVEREST trial?
A. It's basically a high-level overview that describes whether or not the study is prospective, if it's single center, multi-centered, or if it's randomized or nonrandomized, and then the overall objective. In this case, again, it was to assess the safety of the retrieval of the filter.
MS. HELM: Can we turn to page --
THE COURT: Ms. Helm, we're going to break at this point.
MS. HELM: Thank you, Your Honor.
THE COURT: We will resume, ladies and gentlemen, at 2:45, and excuse the jury.
(Recess taken, 2:29 p.m. to 2:45 p.m.)
THE COURT: You may continue, Ms. Helm.
MS. HELM: Thank you, Your Honor.
Your Honor, at the break we had Exhibit 5340 published. May we republish?

THE COURT: Yes.

MS. HELM: And, Scott, could you turn to page 279, please.

JURY MEMBER: Traci, the screen went dead.

THE COURTROOM DEPUTY: Okay. Let me come look.

Is it on? You're good? Okay.

MS. HELM: Can we -- and, Scott, can you highlight the first paragraph -- I'm sorry, highlight the first paragraph, please.

BY MS. HELM:

Q. Mr. Van Vleet, before we took a break, we were talking about the study design for the EVEREST study and the information that was provided.

JURY MEMBER: Excuse me. I'm beeping.

THE COURTROOM DEPUTY: Okay.

JURY MEMBER: I'm sorry.

THE COURTROOM DEPUTY: It happens.

THE COURT: Is that working?

JURY MEMBER: Yes.

THE COURT: Okay. Go ahead, Ms. Helm.

BY MS. HELM:

Q. Mr. Van Vleet, we were talking about the design -- the study design for the EVEREST clinical trial and the information that was included in the 510(k) application for retrievability of the G2.

And on page 279 of the 510(k) application, what did Bard tell the FDA about the patients enrolled in the study and how long they would be followed?

A. So it is a description of the hundred patients that are going to be followed, and those patients would be recruited at up to 15 sites. Patient enrollment would be terminated once 30 patients complete the one-month post-retrieval follow-up visit. All patients enrolled in the study would be followed to six months post-filter placement, or to one month post-filter retrieval, whichever comes first.

Q. Why did Bard conduct follow-up up to six months?

A. That was the official FDA template. It was always 100 patients followed to six months or one month post-retrieval. That was pretty much what all IVC filters evaluated were studied to.

Q. Before we talk about this further --

MS. HELM: And, Scott, you can take it down.

BY MS. HELM:

Q. In your experience of 30 years of working with medical devices, and in your 10 years of working with IVC filters, are you aware of any published prospective clinical study for IVC filters that's five years or ten years or longer?

A. No.

Q. In your experience of 30 years of working with medical devices and your 10 years of working with IVC filters at Bard,

are you aware -- I'm sorry -- of any -- I'm sorry. I've lost myself.

Based on your experience, and based on your experience with Bard, would it be practical to run a clinical study for five years or ten years for an IVC filter?

A. No.

Q. Why not?

A. So the technology evolves pretty quickly. If you had a ten-year clinical trial cycle and then added onto that the product development cycle, you would be delaying access of patients and doctors to new technology for a very long period of time.

Q. And if you got to the end of your ten years, would your technology be current?

A. No. Likely it would be obsolete.

Q. If you did a five-year or a ten-year or a longer prospective study, would you ever get an implantable device like an IVC filter on the market?

A. You would, but it would be extremely long process.

Q. Thank you.

Let's go back and talk about EVEREST and what was told to the FDA.

MS. HELM: And, Scott, could you pull up page 279, please? Again, 5340, page 279. 5340, page 279.

BY MS. HELM:
Q. And, Mr. Van Vleet, in here it says that the device may be left in permanently.
A. Yes.
Q. Do you see that?
A. Yes.
Q. Does this mean that Bard intended the G2 filter to be permanent for patients who did not have their filter retrieved at six months in the study?
A. Yes.
Q. Did it mean that they intended it to be permanent?
A. They meant that they leave it up to the physician that's evaluating the patient to determine if they still require having a filter in place. If their condition would be to continue to need protection, embolic or caval protection, then there is the option to leave it in place permanently.
Q. After six months, after the completion of the study, whose decision was it as to whether to retrieve the filter or leave it in the patients who were part of the study?
A. The surveilling physician or the physician taking care of the patient for that condition.
MS. HELM: Okay. Let's look at page 339, please.
BY MS. HELM:
Q. And, again, is this part of what was submitted to the FDA for the -- for its -- by Bard for its application for the G2

filter to be cleared for retrievability?
A. Yes, it is.
Q. Okay. And can you tell the jury what this section of the 510(k) is.
A. This is the actual clinical study report or the final clinical study report with all of the data that was collected in the EVEREST trial.
Q. So previously we were talking about sort of the protocol, how the study worked, and now we're actually telling them, here's what happened. Here's the study report. Is that right?
A. Yes.
MS. HELM: Okay. And can we turn to page 406, please? And the table in the middle. And, Scott, could you highlight that, please?
BY MS. HELM:
Q. Mr. Van Vleet, what is this table? What information is Bard providing to the FDA in this table in the 510(k) application?
A. So Bard is summarizing the events that were observed in the EVEREST trial and contexting it against the American College of Radiology or the Society for Interventional Radiology Classification, their published classification system.
Q. Why compare it to the SIR guidelines?
A. SIR published a -- and has on several occasions updated the publication of the guidelines based on published literature

that summarized the study of different IVC filters, or the trial results.

And they provide a means for physicians to context the events that you're seeing here and what has been seen across the medical field with different IVC filters.

Q. The jury has seen a number of different documents that talk about the adverse events that occurred during the EVEREST study. And let's just go through and summarize these very quickly.

Was there one fracture?

A. Yes.

Q. There were ten migrations that you previously told about?

A. Yes.

Q. Were there eight penetrations?

A. There were --

Q. I'm sorry, 18 penetrations.

A. -- 18 penetrations, correct.

Q. Is penetration the same thing as perforation?

A. No, it's not. Most filters on the market have little hooks that they use to anchor the filter to the sides of the inferior vena cava. And upon imaging, the hooks push kind of like as a tent pole would push, and it's very difficult unless you have a CT scan to know whether that's actually perforated or penetrated. In most cases it's penetrated, and it's just simply pushing against versus making an actual hole in it.

Q. And the last complication is there were 15 tilts. Were there 15 tilts?
A. Yes.
MS. HELM: And can we go to page 408, please, Scott? And the table in the middle of the page.
BY MS. HELM:
Q. Again, Mr. Van Vleet, what is this information that Bard was providing to the FDA regarding the complications from the EVEREST study?
THE COURT: Hold on just a minute, Ms. Helm.
JURY MEMBER: Sorry, I'm beeping again.
THE COURT: That was short-lived.
THE COURTROOM DEPUTY: Try this one.
THE COURT: How's that? Is that one working?
JURY MEMBER: Yes.
THE COURT: Okay. Go ahead, Ms. Helm.
MS. HELM: Thank you, Your Honor.
BY MS. HELM:
Q. Mr. Van Vleet, do you remember my question?
A. I do.
Q. Okay. Would you go ahead and answer it, please?
A. Sure. So this table is similar to the last one that we saw, but the last one that we saw just gave the absolute numbers of observed events. What this did is take those cases and use the appropriate denominator to calculate the percentage

of occurrence of those rates, which is most helpful because in the SIR publication, the quality standards, they were presented as also percentages, not absolute events.

Q. Okay. And let's go through this very quickly. I want to start with fracture.

What was the percentage -- what was the rate of fracture for the filters evaluated in the EVEREST study?

A. Right. So there was one fracture, but because we only had 82 evaluable images, when you do the math it ends up being 1.2 percent.

Q. And how does this compare to the SIR guidelines or reported rates for fractures in IVC filters?

A. The reported rates in the studies that the SIR surveyed to include here ranged from 2 percent up to 10 percent.

Q. And what was the G2 migration rate in the EVEREST study?

A. 12.2 percent.

Q. And how does that compare to the SIR guidelines for migration?

A. The studies that SIR had evaluated included --

THE COURT: Hold on just a minute. This one isn't working.

JURY MEMBER: Sorry. This one's beeping too.

THE COURTROOM DEPUTY: That's fine. Let's see if we can get one that's going to work for you.

THE COURT: Does that work?

JURY MEMBER: So far.

THE COURT: Okay. Let's go again.

BY MS. HELM:

Q. Mr. Van Vleet, I think you were explaining what the SIR guidelines were for migration.

A. Yes. For migration, the studies that SIR was able to survey included reports of migration up to 18 percent.

Q. And for penetration, what was the rate from the EVEREST study?

A. 21.7 percent.

Q. And what is the rate in the published SIR guidelines?

A. Up to 41 percent.

Q. Okay. I want to talk a little bit more about the migration.

MS. HELM: Scott, could you go to page 797?

And can you turn the page, and can you blow up the chart for us, please?

BY MS. HELM:

Q. Mr. Van Vleet, again, is this part of the 510(k) submission presented to the FDA for retrieval of -- retrievability of the G2 filter?

A. It is.

Q. And can you explain to the jury what this table -- and what information was provided to the FDA in this table?

A. So this was a summary of all of the movements that were

observed in the clinical trial, whether or not they were over the threshold of reportability, which would have been 2 centimeters. It just categorized anything that was seen in terms of movement.

Q. And you said the threshold of movement is 2 centimeters. What do you mean by that?

A. It is. So in order for a clinician or a trained health professional to be able to see movement with the IVC in a plain film, plain x-ray, you would have to have more than 2 centimeters to be sure that it's not simply movement of the IVC.

The IVC is an incredibly elastic vessel, and just in simply breathing in and breathing out, the IVC can move up and down up to 5 centimeters. So you can see how difficult it would be to make a precise measurement. So the radiological community, recognizing that, felt that 2 centimeters or 20 millimeters was an appropriate threshold for reportability.

MS. HELM: Again -- and you can take this down, Scott.

BY MS. HELM:

Q. All of this information relating to the movement, the fractures, all of the information from the EVEREST data was provided to the FDA, was it not?

A. Yes.

Q. When you were here -- was it last week? I've lost track of time.

A. Last week.
Q. And Mr. Lopez was questioning you, he asked you some questions about a Dr. Lehmann.
A. Yes.
Q. His involvement in the EVEREST final report. Do you recall those questions?
A. I do.
Q. Okay. To your knowledge, did Dr. Lehmann actually sign off on the EVEREST final study report?
A. Yes, he did.
MS. HELM: And can we pull up 9080, please?
BY MS. HELM:
Q. And can you see that, Mr. Van Vleet?
A. Yes.
Q. And is this an email?
A. Yes.
Q. And are you included on this email?
A. I am.
MS. HELM: Your Honor, at this time I would move to admit Exhibit 9080.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 9080 admitted into evidence.)
MS. HELM: May I publish, Your Honor?
THE COURT: You may.

BY MS. HELM:
Q. Mr. Van Vleet, is this an email from Dr. Lehmann to Dr. Ciavarella?
A. Yes.
Q. And what is the date of this email?
A. October 24th, 2007.
Q. And would you read to the ladies and gentlemen of the jury what Dr. Lehmann wrote in his email to Dr. Ciavarella.
A. Attached please find the EVEREST final study report, version final 4, with all requests handled as agreed, along with the necessary supporting documents for review and signature by Michelle Michela and Dr. Ciavarella, and forwarding to Bard PV.
Q. And in this email, do you see that there are a number -- I think there are five --
A. There are five attachments, yeah.
Q. -- attachments.
MS. HELM: Okay. Can we go to the very last page of the attachments, which is page 278, please? The next to last page.
BY MS. HELM:
Q. And what is this document, Mr. Van Vleet?
A. It's the final study approval form required by the standard operating procedure in clinical group.
Q. So when we talk about the EVEREST study and the EVEREST

report, is this the final sign-off on the EVEREST report?
A. It is.
MS. HELM: And can we go to page 279, please?
BY MS. HELM:
Q. And on page 279, do you see where it says "John Lehmann, MD, Author"? And what is checked under his name?
A. He's checked it as approved.
Q. And below that, did Dr. Lehmann sign this final report on October 24, 2007?
A. Yes.
Q. So is there any question in your mind that Dr. Lehmann actually did sign off --
A. No.
Q. -- on the EVEREST report?
A. No.
Q. Okay. Thank you.
After the EVEREST study, did you continue to work with Dr. Lehmann on future projects?
A. I did not work for Dr. Lehmann -- or with Dr. Lehmann on future projects.
Q. And why not?
A. Dr. Lehmann wasn't an employee of the division. He was a resource that the corporate clinical team had to work on a variety of projects. So I think he was merely helping out in the authorship of this report.

Q. Okay. Let's talk about the EVEREST report one more time.

Bard had the information. We've just learned that Bard showed the information to the FDA. Were the results of the EVEREST study ever published and made available publicly to the medical community?

A. Yes, they were.

MS. HELM: Can you pull up 6892, please?

BY MS. HELM:

Q. And, Mr. Van Vleet, do you recognize this document?

A. Yes, I do.

Q. And what is this?

A. This is the peer-reviewed publication authored by Dr. Binkert and other of the principal investigators for the study, detailing the results of the EVEREST clinical trial.

MS. HELM: Your Honor, at this time we would move to admit Exhibit 6892.

MR. O'CONNOR: Objection. Hearsay.

MS. HELM: Your Honor, it's not being offered for the truth of the matter asserted, it's being offered to show notice to the medical community about the results of the EVEREST study.

MR. O'CONNOR: Maintain the objection. I think it would be appropriate under --

THE COURT: You got to talk into a mic, Mr. O'Connor.

MR. O'CONNOR: I maintain the objection as to hearsay.

THE COURT: All right. Well, since it's being offered not for the truth of the matter asserted, it's not hearsay.

So the objection is overruled.

But I'm going to give you the same instruction, ladies and gentlemen, on 6892 as on others, which is, this isn't being admitted to prove to you the truth of what's in the article. It's instead being admitted to show what was communicated to the medical community by the article.

And with that clarification, the hearsay objection is overruled.

(Exhibit No. 6892 admitted into evidence.)

MS. HELM: May I publish, Your Honor?

THE COURT: Yes.

BY MS. HELM:

Q. Mr. Van Vleet, in this article, did Dr. Binkert and his coauthors report the results of the EVEREST study?

A. Yes.

Q. And in the results --

MS. HELM: Can you highlight the results, Scott?

BY MS. HELM:

Q. -- did Dr. Binkert and his coauthors report the rate for fracture, caudal migrations, tilts, and penetrations?

A. Yes.

Q. So this information about the G2 filter and the results of the EVEREST study is available in public literature for the

medical community, is it not?
A. It is.
MS. HELM: Okay. You can take that down, Scott.
BY MS. HELM:
Q. After receiving all this information, what did the FDA do in terms of clearing the G2 for retrievability?
A. They cleared the device for -- with the option for retrieval.
MS. HELM: Scott, can you pull up 5339, please?
I believe this is in evidence, Your Honor.
THE COURT: What's the number?
MS. HELM: 5339.
THE COURTROOM DEPUTY: It is.
THE COURT: It is.
MS. HELM: May I publish, Your Honor?
THE COURT: Yes.
BY MS. HELM:
Q. Mr. Van Vleet, is this the letter from the FDA dated January 15, 2008, clearing the G2 filter as a retrievable filter?
A. Yes.
Q. Okay. So this timeline, we went back the first -- we saw a report from February of 2007, and it was finally cleared approximately a year later, in January of 2008; is that right?
A. Yes.

Q. Thank you.

So the jury's been told that the G2 was cleared as a permanent filter. We just learned that the G2 was cleared as a retrievable filter.

Were there additional clearances or additional submissions to the FDA relating to the G2 filter?

A. Yes, there were.

Q. Was there one in August of 2005 and a subsequent one in January of 2008?

A. I can't remember the dates exactly, but that sounds directionally accurate.

Q. And did those two additional applications and clearances of the G2 filter -- I'm sorry, clearances of some aspect or application of the G2 filter relate to the delivery system?

A. Yes.

Q. Okay. And would you explain to the ladies and gentlemen of the jury what is meant by the delivery system? It's not the filter itself.

A. No. It's a tube in which the filter is loaded, and then it's transferred from that tube into a catheter, and the radiologist or whomever is going to use it drives it to wherever he feels it's appropriate to be placed.

And there are several interfaces of the tubes as they fit inside of each other that sometimes can cause there to be a less-than-smooth deployment. So there was an effort by the

team to reduce that riser so that it could be a smooth deployment into the IVC filter -- or into the IVC.

Q. And can an IVC filter be implanted from two different places in someone's body?

A. It can.

Q. And is one of those places the neck?

A. Yes.

Q. And if it's implanted through the neck, how is that referred to?

A. It's through the jugular vein, so that's a jugular deployment system.

Q. So a jugular deployment system.

And if it's implanted -- where is the other place from which it can be implanted?

A. Through the femoral vein, which is in the groin.

Q. Okay. So when we talk about jugular and femoral, those are the two places from which it can be implanted; correct?

A. Yes.

Q. Let's briefly go through these.

MS. HELM: Can I have Exhibit 5354, please?

BY MS. HELM:

Q. And, Mr. Van Vleet, can you tell us what this is?

A. This was a special 510(k) on the G2 filter system, would have been the permanent indication. I think this might have been making -- this predated me, but it might have been making

modifications to the delivery system.
Q. We'll go ahead -- we'll skip that one.
A. Okay.
MS. HELM: Let's take a look at Exhibit 5361, please.
BY MS. HELM:
Q. And can you tell the ladies and gentlemen of the jury what this is?
A. It is also another special 510(k) on the G2 filter system. I believe it's a modification. Again, this predates my time.
Q. Okay.
All right. So there were multiple submissions relating to the G2 to the FDA, in addition to permanent and retrievability; correct?
MR. O'CONNOR: Objection. Leading.
BY MS. HELM:
Q. Were there multiple submissions to the FDA relating to the G2 filter?
A. Yes.
Q. In addition to its clearance for -- as a permanent filter and as a retrievable filter?
A. Yes.
Q. Let's move forward and let's talk about the G2X or the G2 Express. And the jury has heard those terms interchangeably.
Were you at Bard at the time the G2X was developed and submitted for clearance to the FDA?

A. Yes, I was.

MS. HELM: And, Your Honor --

Scotty, can you pull up 5373, please?

Your Honor, I believe this is in evidence. May I publish?

THE COURT: Yes, it is. You may.

BY MS. HELM:

Q. Mr. Van Vleet, what is this document?

A. It is a 510(k) submission for the G2 Express.

Q. And was this 510(k) for the G2 Express for both delivery systems?

A. Yes, for femoral and jugular.

Q. Okay. And were you involved in the preparation of this 510(k) submission to the FDA?

A. Yes.

MS. HELM: And can we turn to page 68, please?

And can you turn that, and can you blow it up a little bit?

BY MS. HELM:

Q. Mr. Van Vleet, can you explain to us what this is on page 68 of Bard's submission to the FDA regarding the G2X filter?

A. Yes. It's a summary of measurements that were taken and some testing that was performed on the device.

Q. And is this a -- this is actually telling the FDA about

bench testing that was performed on the G2X?
A. Yes.
MS. HELM: And can we turn to page 70, please?
And can you flip that page?
BY MS. HELM:
Q. And, Mr. Van Vleet, on this page, in the description of testing, what test is being described to the FDA on page 70?
A. Sure. It's called cyclic fatigue. It's --
Q. And -- I'm sorry, go ahead.
A. It's a test to replicate what conditions the filter can undergo in a human body over a period of years.
MS. HELM: And, Scott, can you highlight the paragraph in the right column that says "The test method"?
BY MS. HELM:
Q. And, Mr. Van Vleet, what is Bard telling the FDA about the test method that it used for this cyclic fatigue test on the G2X filter?
A. So the FDA's expectation is that you will test a medical device in a worst case situation. And this is frequently derived from experts or the literature, but it was felt that the worst case situation would be a patient undergoing severe chronic cough syndrome. And that would be approximately 43 hard diaphragmatic coughs per hour over a period of ten years, in which the test is also simulating the respiration that happens in the patient.

So the testing was set up to evaluate the filter in a human, breathing for ten years, and also coughing 43 times an hour, 24 hours a day.

Q. For ten years?

A. For ten years.

Q. And --

MS. HELM: Okay. Thank you. You can take that down.

Oh, I'm sorry. Will you put that back up?

BY MS. HELM:

Q. Where did Bard -- do you know where Bard got the information or the criteria it used for this test that it's reporting to the FDA?

A. Sure. We usually start discussing with a pulmonologist or somebody familiar with breathing of patients, both normally and severe. And then at the same time do a complete search in the literature and see whatever may have been published about the boundary conditions that you would need to --

Q. And there are footnotes at the bottom of the page. Is that the literature from which this information or test criteria were retrieved?

A. Yes.

Q. Obtained?

A. Yes.

Q. Thank you.

MS. HELM: And, Scott, could we turn to page 130 and

131?
BY MS. HELM:
Q. Mr. Van Vleet, the jury's heard about IFUs. Would you just again explain to them what an IFU is?
A. An IFU is a document that's included with every product that's sold. IFU stands for instructions for use or indications for use.
Q. And in its application for clearance of the G2X, did Bard provide the FDA with a draft IFU for the G2X?
A. Yes.
Q. And after providing FDA with this information, the testing, the IFU, and the other information relating to the G2X, did the FDA clear the G2X for commercial use?
A. Yes.
MS. HELM: Can we pull up 5368, please?
BY MS. HELM:
Q. Mr. Van Vleet, can you identify that document?
A. Yes. This is the clearance document for the G2 Express femoral and jugular delivery systems.
Q. And what's the date on that document?
A. July 3rd, 2008.
MS. HELM: And, Your Honor, at this time we move to admit 5368.
MR. O'CONNOR: No objection.
THE COURT: Admitted.

(Exhibit No. 5368 admitted into evidence.)

MS. HELM: May I publish?

THE COURT: You may.

BY MS. HELM:

Q. Mr. Van Vleet, before we move on, would you remind the jury about what the G2X is? What was the difference between the G2 and the G2X? Just so we keep building our timeline.

A. Sure. So the G2 had just a simple little nub at the very top of it, and it was designed to be retrieved with a grasping device called a cone. And when you grasped around the neck and shoulders of that and you pushed the tube or the catheter over the cone, it would squeeze those little pinchers together, and that's how you could remove it. It was a specifically designed tool for that filter.

Many radiologists prefer to work with snares. It's just something that they all learn in their training. And so the desire was to create a hook for those people that were more comfortable to retrieve it with a snare.

Q. And that was the G2X?

A. And that's the G2X.

Q. Okay. Subsequent to its clearance, was the G2X -- also was information about the G2X presented to the FDA relating to the delivery systems?

A. Yes.

Q. Let's move forward.

We've talked -- the jury's heard about the clearance for the G2, the G2X, and now I would like to talk to you about the next generation, which was the Eclipse.

Were you personally involved in the regulatory filings for the Eclipse filter while you were at Bard?

A. Yes.

Q. Before Bard submitted any application to the FDA for clearance of the Eclipse filter, did you have conversations with the FDA about it?

A. Multiple times.

Q. Why?

A. Anytime we wanted to submit an application to the FDA, we -- it's best practice to get -- have an agreement with them as far as what testing you need to submit and what they're going -- expecting to see.

And that filter in particular, we were changing the surface finish on it, and it was a topic that the FDA has been very interested in. They had gone through a period of time where they required stent manufacturers to also electropolish their devices.

Q. So as we build our timeline, as we come forward in time, are we in 2009, approximately?

A. Yeah. Yes. Yes, 2009.

Q. And in addition to the Eclipse, at this same time period, were you having conversations with the FDA about the various

other projects that Bard was working on?
A. Yes.
MS. HELM: Scotty, would you pull up 5593, please.
BY MS. HELM:
Q. Mr. Van Vleet, do you recognize this document?
A. Yes.
Q. And can you tell the ladies and gentlemen of the jury what this is, please.
A. It is meeting minutes from a meeting with FDA, with our reviewer.
Q. And --
A. It's required as part of their process and our process that we memorialize every meeting that we have and then send them the meeting minutes to see if they agree with our summarization.
Q. And were you either involved in drafting or approving these meeting minutes?
A. Yes.
Q. And were they prepared contemporaneously or soon after the meeting took place in August of 2009?
A. Yes.
Q. Is this document maintained in the regular course of business at Bard?
A. It is.
MS. HELM: Your Honor, at this time I move to admit

Exhibit 5593.

MR. O'CONNOR: Objection. Hearsay and hearsay within hearsay.

THE COURT: All right. I'm going to overrule the first hearsay objection under 803(6). She just laid the foundation to that.

What's your response on hearsay within hearsay?

MS. HELM: Your Honor, to the extent the plaintiffs are concerned about hearsay within hearsay, we would be fine with redactions of it. The portion that I intend to ask him about is not hearsay, in my opinion.

THE COURT: Okay. Which portion is it? Why don't you put it up on the screen so they can look at it.

MS. HELM: Okay.

THE COURT: I'm going to admit it subject to redaction of any hearsay within the hearsay.

MR. O'CONNOR: Thank you.

THE COURT: Let's have you look at the section and make sure you don't have an objection to that section.

MS. HELM: Just paragraph 2, Your Honor.

BY MS. HELM:

Q. Mr. Van Vleet, do you know Joni Creal?

A. Yes.

Q. Is she an employee of Bard -- or was she an employee of Bard in August of 2009?

A. She was, and she still is.

MR. O'CONNOR: Objection. This paragraph is hearsay within hearsay.

MS. HELM: Your Honor, I believe the paragraph is recounting what Ms. Creal, a Bard employee, stated.

THE COURT: That makes it hearsay within hearsay.

MS. HELM: You know what, Your Honor, I'll move on.

THE COURT: All right.

BY MS. HELM:

Q. Mr. Van Vleet, did you -- in August of 2009, did you discuss with the FDA a project called the G2 Platinum?

A. Yes.

Q. Why did Bard discuss with the FDA the project called the G2 Platinum?

A. The FDA was very interested in moving to electropolish all implants that go into the human body. It's a process to make the finish a lot smoother and remove imperfections.

MR. O'CONNOR: Objection to the testimony about what the FDA was interested in. That is hearsay. Move to strike.

THE COURT: Hold on just a minute.

Well, the question was why Bard did it. I think this is from Bard's perspective.

You can cross-examine him on that.

MR. O'CONNOR: All right. Thank you.

BY MS. HELM:
Q. And in August of 2009, what did Bard tell the FDA about the G2 Platinum project?
A. So there had been a decision to not move forward with that project. It was too difficult to terminally electropolish the filter. There were imperfections left in corners, and it wouldn't have been a validatable and safe way of doing it.
Q. In light of the fact that the G2 Platinum project was not successful, did Bard look to an alternative or a different way to accomplish electropolishing?
A. Yes.
Q. And was that what eventually became the Eclipse filter?
A. That was what eventually became the Eclipse filter, yes, correct.
Q. And in August of 2009, did you also discuss this concept of the Eclipse filter with the FDA?
A. Yes.
Q. And what was the purpose? Why did you want to talk to them about the Eclipse filter?
A. Because we knew that they had a lot of specific requirements on how they wanted the final electropolished product tested. They'd want to test for leaching, surface quality finish, a lot of things that their experts would want to direct us in terms of what to include in testing protocols.
Q. In August of 2009, did Bard also have a project in the

research and development group relating to caudal anchors?
A. Yes.
Q. And did you tell the FDA about that project?
A. We did.
Q. And was that project ready to be presented to the FDA?
A. Not immediately, but in principle, yes.
Q. And did you also tell the FDA about a project relating to a laser-cut filter with caudal anchors?
A. Yes.
Q. So in August of 2009, what project was Bard working on that was the laser-cut filter with caudal anchors?
A. It would have been the product concept that eventually became the Denali filter.
Q. But in 2009, was that project ready to be presented to the FDA?
A. No.
Q. So why do you tell the FDA about all these projects, the Platinum that you were no longer pursuing, the Eclipse that you were pursuing, and the future projects of the Meridian and the Denali?
A. It helps them to kind of get a visibility as to the staffing that they'll need to review. These are lengthy documents, and it takes a long time. And so it's really a courtesy. We maybe don't necessarily have to do it, but they very much appreciate knowing the relative timing of your

submissions.
Q. And did Bard eventually develop a process to electropolish its filters?
A. Yes.
Q. And, again, was that the Eclipse?
A. That was Eclipse, correct.
Q. And did Bard submit the Eclipse filter to the FDA for approval through a 510(k) process?
A. Yes.
Q. And, again, what was the difference between the G2X filter that had been cleared and the Eclipse filter?
A. They were dimensionally identical. The only difference was in the treatment of the surface finish, electropolishing would remove imperfections and any irregularities.
MS. HELM: Scott, could you pull up 5272, please.
And, Your Honor, I believe this has been admitted. May I publish?
THE COURTROOM DEPUTY: Yes.
THE COURT: You may.
BY MS. HELM:
Q. Mr. Van Vleet, what is this document?
A. It is a 510(k) submission on the Eclipse filter system.
Q. And when was this submitted to the FDA?
A. November 23rd, 2009.
MS. HELM: Okay. And could we turn to page 2, please.

BY MS. HELM:
Q. And this is a Table of Contents?
A. Yes.
Q. And generally speaking, what types of information did Bard provide to the FDA about the Eclipse filter?
A. You would provide the design concept to the labeling, the engineering drawings, any information about how that device is different than a predicate device, and any additional testing that would have been done.
Q. And did the FDA eventually clear the Eclipse filter for commercial use?
A. They did.
MS. HELM: And, Scott, can you pull up 5273, please?
BY MS. HELM:
Q. And, Mr. Van Vleet, what is this document?
A. That is the FDA's clearance letter for the Eclipse filter system.
MS. HELM: Your Honor, I move to admit 5273.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 5273 admitted into evidence.)
MS. HELM: May I publish, Your Honor?
THE COURT: Yes.
BY MS. HELM:
Q. Mr. Van Vleet, when was the Eclipse filter cleared by the

FDA for commercial use in the United States?
A. January 14th of 2010.
Q. Before January 14, 2010, could Bard sell the Eclipse filter?
A. No.
Q. Did Bard submit an additional --
MS. HELM: Scotty, you can take that down.
BY MS. HELM:
Q. -- additional 510(k) submission to the FDA regarding the Eclipse filter?
A. I think there may have been a modification to the delivery system. I'd have to --
Q. Was there a second 510(k) that related to a patient brochure and ID card for the Eclipse filter?
A. Yes. Sorry, I forgot about that one. Yes.
MS. HELM: Scott, would you pull up 5586, please?
Your Honor, I believe this is in evidence. May I publish?
THE COURT: Yes.
BY MS. HELM:
Q. Mr. Van Vleet, is this the submission that I just mentioned relating to a brochure for the Eclipse filter?
A. Yes.
Q. And when was that submitted to the FDA?
A. May 20th, 2010.

Q. Why did Bard want to submit its patient brochure and patient ID card to the FDA for clearance?
A. It's considered to be part of labeling, just like the IFU is. And labeling has to be developed in collaboration with the FDA.
Q. The name stayed the same?
A. Yes.
Q. Did the product stay the same?
A. Yes.
MS. HELM: And can we turn to page 78, 79, and 80.
BY MS. HELM:
Q. Mr. Van Vleet, were those pages the proposed brochure and patient card that Bard sought clearance for the FDA -- from the FDA?
A. Yes.
Q. Okay. Do you know how this patient brochure and card were going to be used by Bard after they were cleared by the FDA?
A. Sure. It's included in every product, but it was also provided to implanting institutions that we knew had bought Bard products. The desire is that the card is removed from its perforations, completed, and then given to each patient to be able to carry with them. Any patient that has to have an MRI has to carry an implant card so that the technicians know exactly how to do that type of test on them.
Q. Before the FDA cleared the patient brochure and

identification card, did they ask some questions or have some requests of Bard?

A. I'd have to remember.

Q. Sure.

A. I know there were conversations about the implant card and there were some edits that they proposed.

MS. HELM: Scott, could you pull up 5587, please?

BY MS. HELM:

Q. Mr. Van Vleet, do you recognize this document?

A. Yes.

Q. And what is this?

A. This is questions based on the submission of the implant card and the patient brochure.

Q. Does this refresh your recollection that the FDA had some questions about the brochure?

A. Yes.

MS. HELM: Your Honor, at this time I'd move to admit 5587.

MR. O'CONNOR: No objection. I thought it was already in.

THE COURT: It is not.

5587 is admitted.

(Exhibit No. 5587 admitted into evidence.)

MS. HELM: And may I publish?

THE COURT: You may.

BY MS. HELM:

Q. And in Section 1, what was the FDA asking Bard to do regarding the patient brochure?

A. There is a section of the brochure that says: When can the filter be removed?

And Bard had proposed the language that said: The Eclipse vena cava filter does not have a time in which it must be removed.

FDA was objecting because we had not provided clinical data to support this statement. In the labeling on filter retrieval for 58 patients with a mean retrieval of 148 days -- or 140 days, which was submitted, but FDA did not feel like this was sufficient to substantiate the statement that the filter does not have a time limit for retrieval -- or removal.

Q. Did Bard eventually remove that language from the patient brochure?

A. I believe we did. I think we believed that -- we modified it to state that the patient needs to consult their physician, and the physician would determine when it should be retrieved.

Q. And was the patient brochure eventually cleared by the FDA, the patient brochure for the Eclipse?

A. Yes.

MS. HELM: And can you pull up 5589, please, Scott.

BY MS. HELM:

Q. And, Mr. Van Vleet, what is this document?

A. This is a clearance of the Eclipse filter system. Looking at the date here. Yeah, I think that's the patient brochure.

MS. HELM: Your Honor, at this time I move to admit 5589.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5589 admitted into evidence.)

BY MS. HELM:

Q. And once it was cleared, did Bard have a patient brochure to include with its packaging and provide to doctors who were implanting Eclipse filters?

A. Yes.

MS. HELM: Scott, could you pull up 8362, please.

BY MS. HELM:

Q. And, Mr. Van Vleet, what is this document?

A. That is the patient brochure.

Q. And is this the patient brochure that we just discussed that was cleared by the FDA relating to the Eclipse filter?

A. Yes, I believe so.

MS. HELM: Your Honor, at this time I'd move to admit 8362.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 8362 admitted into evidence.)

BY MS. HELM:

Q. Mr. Van Vleet --

MS. HELM: May I publish, Your Honor?

THE COURT: You may.

BY MS. HELM:

Q. Mr. Van Vleet, is -- why did Bard decide to provide a patient brochure with the Eclipse filter?

A. For I believe all potentially permanently implanted devices that patients leave the hospital with, there is a brochure that Bard, as a matter of course, had historically presented, and then it became something FDA expected to be included with every one of those type of products.

Q. Was this brochure intended to replace the advice and warnings that a doctor provides to a patient?

A. No.

Q. On the first page, on the left-hand side, does the brochure talk about information about pulmonary embolism?

A. Yes.

Q. And then does it talk about what an IVC filter is?

A. Yes.

Q. And then on the right side, does it talk about the implantation procedure or process?

A. Yes.

MS. HELM: And could we turn to page 2, please, Scott.

BY MS. HELM:

Q. And in the middle of the brochure, there's a blue bolded section, said: What are the risks associated with implantable filters?

Do you see that?

A. I do.

Q. And moving down to the fifth bullet point, if you talked -- count down, can you tell the ladies and gentlemen of the jury what it says?

A. Yes.

The entire filter or pieces of the filter may break loose and travel to the heart or lungs, causing injury or death. You may need to have additional surgery to retrieve the filter or pieces if they break loose.

Q. Why was Bard providing information about complications with its filter -- potential complications with the Eclipse filter to -- in the patient brochure?

MS. HELM: Scott, you can take it down.

THE WITNESS: With any type of labeling, which this is considered labeling, that you provide, you have to have a fair balance. So you can't just simply say the good things that a product does. You also have to also be very transparent about potential risks or complications that having the product may have.

MS. HELM: Actually, can you pull back up 8362,

page 2?
BY MS. HELM:
Q. And on the far right, in the top corner, Mr. Van Vleet, do you see the section that says, "Does the filter have to be removed?"
A. Yes.
Q. And what did Bard tell -- include in its patient brochure about whether the filter had to be removed?
A. Yes. So the question is: Does the filter have to be removed?
The answer is: No. The Eclipse vena cava filter is designed to be a permanent implant and does not have to be removed, repositioned, or replaced. However, in the cases where the risk for pulmonary embolism is temporary, your physician may choose to remove the filter. You should discuss filter removal with your physician.
Q. Why did Bard advise patients that they should discuss filter removal with their physicians?
A. The idea and decision to place a filter and any other medical device is the decision of a physician. In the interest of caring for their patient, the conversation has to be between the patient and the physician.
Q. Thank you.
MS. HELM: Scotty, you can take that down.

BY MS. HELM:

Q. I'm going to shift gears a little bit. You mentioned in the FDA clearance submissions, the IFUs, and you've explained to the jury what those are.

Before we look at an IFU, I want to follow up on something you said last week when you testified. You mentioned that Bard and the FDA, I think your words were, coauthored IFUs in the past.

Do you recall that testimony?

A. Yes.

Q. Can you give us an example of where Bard and the FDA coauthored an IVC IFU -- IVC filter IFU?

A. On every submission, on every 510(k) to the FDA, there would be a draft proposed by Bard or the sponsor, and always a discussion that's provided in soft copy to the FDA so that they can go in and make modifications to it. And usually there's at least one or two meetings held about that.

Q. In fact, we saw in some submissions where the draft of the IFU was actually included in the 510(k) submission, didn't we?

A. Yes.

MS. HELM: Scott, can you pull up 8325, please.

BY MS. HELM:

Q. Mr. Van Vleet, what is this document?

A. This is the IFU for the Eclipse vena cava filter.

Q. And were you involved in -- were you employed at Bard at

the time this IFU was drafted with the FDA?
A. Yes.
Q. And were you involved in that process?
A. I was.
MS. HELM: Your Honor, at this time I'd move to admit 8325.
THE COURTROOM DEPUTY: I show 8325 in.
THE COURT: 8325 is already in evidence.
MS. HELM: Thank you, Your Honor. I apologize for not catching that.
May I publish?
THE COURT: You may.
MS. HELM: And, Scott, can you go to page 4? And can you go down to where it says "Warnings." That's at the top. And can you go to number 11, please.
That's not the right one.
Can you go to number 8, please.
BY MS. HELM:
Q. Mr. Van Vleet, did Bard include a warning in the Eclipse IFU about filter fractures?
A. Yes.
Q. And what did Bard warn doctors about filter fractures -- filter fractures in the Eclipse IFU?
MR. O'CONNOR: Objection. Irrelevant.
THE COURT: Overruled.

THE WITNESS: It states that filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.

BY MS. HELM:

Q. And in the same IFU --

MS. HELM: Scott, can you pull that out?

BY MS. HELM:

Q. -- did Bard also inform doctors about the potential of movement, migration, or tilt?

A. Yes.

MS. HELM: And, Scott, can we go to page -- there we go.

BY MS. HELM:

Q. Can you tell the jury what Bard told doctors about movement in the Eclipse IFU?

A. Sure.

Movement, migration, or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment

into clots, and/or dislodgement due to large clot burdens.
Q. In the Eclipse IFU, did Bard specifically mention reports of caudal migration?
A. Yes.
MS. HELM: And, Scott, can we go to page 4, please? And under the bolded section, Note.
That's not the right one. My page and your page are different.
You know what, I'm going to move on. I'm not going to take the jury's time because I don't have the right complication.
Can you go to page 6, though, please. And -- never mind.
BY MS. HELM:
Q. Mr. Van Vleet, do you recall whether the Eclipse IFU also included the results from the EVEREST trial for the G2 filter?
A. Yes.
Q. So in addition to being provided to the FDA, available in the medical literature, were the results of the EVEREST trial also included in every Eclipse IFU that was -- went with every Eclipse filter delivered to any doctor who was implanting a filter?
A. Yes.
Q. Let's back up. And I'm going against chronology, but let's briefly talk about the G2X IFU.

MS. HELM: Scott, can you pull up 5931, please?

BY MS. HELM:

Q. Mr. Van Vleet, do you recognize this document?

A. I do.

Q. And what is this?

A. It's the IFU for the G2X filter system.

Q. Were you involved in the preparation or drafting of this IFU during your time at Bard?

A. Yes.

MS. HELM: Your Honor, at this time I move to admit 5931.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5931 admitted into evidence.)

MS. HELM: May I publish?

THE COURT: Yes.

MS. HELM: And can we go to page 4, Scott? And we'll hope that my numbers on the same as yours.

And under "Warnings," number 9. Can you just blow up 8 and 9?

BY MS. HELM:

Q. Mr. Van Vleet, are these the same warnings that we just read in the Eclipse IFU for fracture and movement, migration, or tilt of filters?

A. Yes. They appear to be, yes.

Q. Thank you.

And, again --

MS. HELM: You can take that down, Scott.

BY MS. HELM:

Q. -- did the G2X IFU also include the information from the EVEREST study that we talked about in the Eclipse IFU?

A. Yes.

Q. Thank you.

Let's move forward. We're getting there.

Starting in 2010, did Bard continue to provide information to the FDA regarding its filters?

A. Yes.

Q. And in what ways did Bard continue to provide that information to the FDA regarding the performance of its filters?

A. Well, as we've seen in many different submissions, serial 510(k) changes in submissions, but also in informal and also formal face-to-face meetings.

Q. And throughout this entire process, was Bard also providing adverse event information to the FDA on a regular basis?

A. Yes.

Q. And Mr. Modra was here and testified about an MDR. Would you remind the jury what that is?

A. It's a medical device report. It's required by FDA, either for a manufacturer or a physician or a hospital to report to

FDA every time a medical device malfunctions.

MS. HELM: Would you put up 5602, please?

BY MS. HELM:

Q. Mr. Van Vleet, is this another contact report regarding a meeting that was held between Bard and the FDA?

A. Yes.

Q. And when did this meeting take place?

A. January the 7th, 2010.

Q. And do you recall -- do you recall this meeting?

A. I definitely recall this meeting.

Q. And who requested this meeting?

A. I requested this meeting.

Q. Did you attend the meeting?

A. I did.

Q. And was this contact report prepared by you or at your direction contemporaneous to or soon after the meeting?

A. Yes.

MS. HELM: Your Honor, at this time I move to admit 5602 as redacted.

MR. O'CONNOR: Objection. Hearsay within hearsay.

THE COURT: What's your response on that, Ms. Helm?

MS. HELM: I'm not sure what section he's referring to because I understood that we had addressed that with prior redactions.

THE COURT: What is the portion you're referring to,

Mr. O'Connor?

MR. O'CONNOR: Well, Your Honor, there's a number of them. If you look at just the first full paragraph beginning with "Doctor."

THE COURT: Why is that not hearsay within hearsay, Ms. Helm?

MS. HELM: Your Honor, I'll move on and just ask Mr. Van Vleet about the meeting.

THE COURT: Okay.

BY MS. HELM:

Q. Mr. Van Vleet, what was the purpose of this meeting in January of 2010 that you asked for with the FDA?

A. We had heard of a study that was conducted at a hospital in Pennsylvania, first through a cath conference that was online and available to replay and listen to, and then subsequent to that, the article was actually published.

But the most important thing, whenever we see an article or a case study that includes Bard products and includes any kind of malfunction of that product, or apparent malfunction, we have a responsibility, a legal responsibility to report this to the FDA.

So, number one, the summarization of results from this specific physician and hospital's experience was on orders of magnitude completely different than anything that we'd ever seen, easily by a log, by ten times.

And most importantly, we had made a number of efforts to visit the hospital and collect this information in our efforts to honor our requirement to report this to the FDA. And we had gotten nowhere.

Q. And this doctor and this study, was this the Nicholson study?

A. Yes.

Q. So in January of 2010, you -- why -- you requested a meeting with the FDA to specifically discuss the Nicholson study?

A. Yes.

Q. And do you recall what efforts Bard made to contact Dr. Nicholson or the York Hospital to get the information that was necessary for Bard to comply with its reporting requirements to the FDA?

A. I do. We made 13 distinct efforts, four of them in person on site.

Q. And was Bard able, through those 13 distinct efforts, four on site, to obtain the information it needed to comply with the regulations and report the information identified by Dr. Nicholson in his study?

A. No.

Q. During this meeting -- or in preparation of this meeting with the FDA, what did Bard do to get ready for the meeting?

A. It reviewed all of the reports to Bard, either from

customers or reported by customers, as MDRs or complaints and summarized those. It looked at sales data to have an idea of denominators. It once again refreshed its literature search on the IVC filter environment and interviewed experts that were familiar with the device and had implanted the device numerous times.

Q. Did Bard take the Nicholson study seriously?

A. Very seriously.

Q. Did Bard try to bury the Nicholson study or hide from it?

A. Never.

Q. Thank you.

I want to switch gears. We're going to move forward in time. We're getting closer to the present.

The jury's heard about the Meridian and the Denali. Were you employed at Bard when the Meridian and the Denali were submitted to the FDA for clearance?

A. Yes.

Q. And do you remember approximately when the FDA -- the 510(k) application for the Meridian was submitted to the FDA?

A. Toward the end of '10 or beginning of '11, maybe.

Q. And do you recall when the Meridian was actually cleared?

A. I think maybe the first half of '11 or --

Q. Was it August -- does August 2011 sound --

A. It was definitely 2011. August is probably the right date.

Q. And prior to the clearance of the Meridian in August of

2011, did you have conversations with the FDA about the Meridian?

A. Yes.

Q. And do you recall having meetings where FDA personnel were involved?

A. Yes.

Q. And who is Dr. Pablo Morales at the FDA?

A. Dr. Pablo Morales is a medical reviewer employed full time by the FDA. He is a practicing interventional radiologist that's also a vascular surgeon.

Q. And did you have meetings that included Dr. Morales with the FDA to talk about the Meridian filter before it was cleared by the FDA?

A. Yes.

Q. And do you recall the FDA having some concerns about some corrosion or surface characterizations of the filter?

A. Yes.

Q. Prior to its clearance in May of 2011, could Bard have sold the Meridian filter?

A. No.

Q. And let's talk briefly about the Denali. The jury's heard about that.

Is the Denali the next generation after the Meridian?

A. Yes.

Q. And is there a difference between the Denali and the

previous filters as to the wire or how it's made?
A. Yes. The previous iterations were assembled wires of Nitinol that were welded in certain places. And the Denali filter is -- I guess the best way to describe it would be a solid state. It's made out of one piece of Nitinol. It's just simply laser cut, so it's got more integrity.
And then also because it's not a welded-together group of wires with lots of little cracks and crevasses, it's possible to terminally electropolish it, which is the best way of electropolishing, to treat the surface finish.
Q. And am I correct that the Denali was not cleared by the FDA until May of 2013?
A. Correct, yes.
Q. But we talked about earlier, back in 2009, you were talking to the FDA about the concept and the idea of the Denali. Do you recall that?
A. Yes.
Q. So was there a four-year, at least, process in the development and clearance of the Denali?
A. Yes.
MR. O'CONNOR: Objection. Leading.
THE COURT: Sustained.
BY MS. HELM:
Q. Was there an at least four-year process in the development and clearance of the Denali filter?

MR. O'CONNOR: Same objection.

THE COURT: Overruled.

THE WITNESS: There was at least a five-year development process for the Denali.

BY MS. HELM:

Q. Thank you.

I want to switch gears. And we've been through the -- we've been through all of the filters, and let's switch gears and talk about a few more things in the regulatory and clinical world for IVC filters.

Are you familiar with what FDA down-classification is?

A. Yes.

Q. Would you explain that to the jury, please.

A. Medical devices are classified into one, two, or three levels. The third level would be the more significant risk devices. The second one could be some significant risk devices, but it's felt that they're well understood and that there had been performance standards and testing standards developed that made it very easy to standardize the manufacture of these. Class I devices are canes, Band-Aids, just more simpler medical devices.

When a petition is either brought from within the FDA or from outside of the FDA, based on information to lower the risk level of the device, there's a process whereby FDA listens to all of this and processes it and can make a decision to, in

fact, down-class or not down-class a device.
Q. And when you joined Bard, did you learn that IVC filters had been -- before you got there had been down-classed?
A. Yes.
MS. HELM: And, Scott, would you pull up 5877, please.
Your Honor, I believe this is in evidence. May I publish?
THE COURT: You may.
BY MS. HELM:
Q. Mr. Van Vleet, are you familiar with this document?
A. Yes, I am.
Q. And in the course of your employment with Bard and working with IVC filters, did you have an opportunity to review this document?
A. Yes.
Q. And is this the document that down-classified IVC filters?
A. Yes.
Q. And what's the date on the document?
A. December 2, 1996.
Q. So by the time you had been at Bard, IVC filters had been down-classified for about 11 years?
A. Yes.
MS. HELM: And could we turn to page 3 of 5877, please. And the sentence that starts, "Although the risks," at the very top. And just the rest of that paragraph, that's

fine.
BY MS. HELM:
Q. Mr. Van Vleet, you see the sentence that says "Although the risks"?
A. Yes.
Q. And what is the FDA saying about the risks of IVC filters in this sentence?
A. Although these risks are potentially life threatening, as is the disease they are intended to treat, they are well known to the users and are well characterized in the medical literature. FDA now believes that these risks can be controlled by special controls.
MS. HELM: And can you go to page 4, Scott? And page 5, page 6, and page 7.
BY MS. HELM:
Q. Mr. Van Vleet, are those a number of risks that the FDA identified with IVC filters in the memo dated 1996?
A. Yes.
MS. HELM: Now, Scott, can we go back to page 5, please. And under the section at the bottom where it says "Filter Migration." It goes on to page 6.
BY MS. HELM:
Q. Mr. Van Vleet, do you see where the FDA's talking about migration of the filters back in 1996?
A. Yes.

Q. And there's a sentence in there that starts, "Much of the reported."

Do you see that?

A. Yes.

Q. Would you read that sentence, please?

A. Much of the reported filter movement may actually be due to measurement error resulting from differences in patient positioning, breathing, and parallax.

Q. Mr. Van Vleet, what do you understand parallax to mean?

A. I'm not a radiologist, but parallax is a distortion that is caused in an x-ray image or any other radiographic image based on the angle that the x-ray beam comes through the patient.

Q. And, again, is the FDA -- does the FDA state that measurement error is a possibility -- is a complication in trying to identify filter movement or migration?

A. Yes, I believe so.

Q. And does that relate back to your testimony earlier today about how difficult it is to measure the movement because of the breathing of people and other movements?

A. Yes, it does.

MS. HELM: And, Scott, can we go to page 6, please? And under Section F.

BY MS. HELM:

Q. Mr. Van Vleet, what is the reported rate of caval penetration that the FDA reported in this memo dated 1996?

A. They report a caval penetration rate of 9 percent.
Q. And what does FDA say about whether this penetration is symptomatic? Do you see that above?
A. Yes.
So they say that slight penetration of the caval wall by filter struts is usually asymptomatic and clinically insignificant, perhaps because penetration occurs gradually, allowing the time for the vessel wall to fibrose.
Q. And, again, this is a memo from the FDA dated 1996?
A. Yes.
MS. HELM: Can we go to page 7, Scott? And under the Filter Fracture.
BY MS. HELM:
Q. And, Mr. Van Vleet, what did the FDA say in 1996 were the reported rates of filter fracture in the literature?
A. Yes. The incidence of occurrence has been reported at 2 percent.
Q. And did the FDA -- what did the FDA say might happen to a fractured strut? Do you see that?
A. Yes. They -- the fracture fragments may migrate locally or distally.
Q. Do you know what distally means?
A. It means from north to south.
Q. So to other parts of the body?
A. Yes.

Q. Thank you.

Okay. I'm going to change gears one more time and talk to you about the FDA guidance regarding IVC filters. Is that a document you're familiar with?

A. Yes.

MS. HELM: And, Scott, can you pull up 5126, please?

BY MS. HELM:

Q. Mr. Van Vleet --

MS. HELM: Your Honor, I believe this is admitted. May I publish?

THE COURT: You may.

BY MS. HELM:

Q. Mr. Van Vleet, are you familiar with this document?

A. I am.

Q. Would you tell the jury what this is, please?

A. So for Class II devices, FDA has developed a series of guidance documents, and they attempt to describe for manufacturers what their expectations are in terms of what testing must be performed and what kind of evidence must be submitted in these regulatory applications. And this is their one for intravascular filter.

Q. And in your role as vice president of regulatory and clinical affairs for Bard, did you rely on this document when you were submitting 510(k) submissions for the Bard IVC filters we've talked about today?

A. Yes.
Q. And did you use this for the submission for the G2 as a retrievable filter?
A. Yes.
Q. For the G2X?
A. Yes.
Q. The Eclipse?
A. Yes.
Q. The Meridian?
A. Yes.
Q. And the Denali?
A. Yes.
MS. HELM: And, Scott, if we could turn to page 9, please, under number 4, Filter Migration.
BY MS. HELM:
Q. And in this FDA document, Mr. Van Vleet, does the FDA again talk about the difficulty in measuring movement of an IVC filter?
A. Yes.
Q. And does it again talk about patient positioning, breathing, and parallax?
A. Yes.
Q. Is that language, as you understand it, similar to the language we just read in the 1996 memo?
A. It looks like it's the same sentence.

Q. I'm going to shift gears on you one more time and try to get us up to date.

And I'd like to talk to you about an FDA safety communication from 2010 regarding IVC filters. Do you recall that?

A. I do.

MS. HELM: Scott, could you pull up 6991.

BY MS. HELM:

Q. Mr. Van Vleet, do you recognize this document?

A. Yes, I do.

Q. Is this the safety communication from the FDA that I just discussed?

A. Yes.

MS. HELM: Your Honor, I believe this is in evidence. May I publish?

THE COURTROOM DEPUTY: 6991?

THE COURT: We don't have that in evidence.

BY MS. HELM:

Q. Mr. Van Vleet, do you recognize this document?

A. I do.

Q. And is this a communication from the FDA that's available publicly regarding IVC filters?

A. Yes.

MS. HELM: And, Your Honor, at this time I move to admit 6991.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 6991 admitted into evidence.)

MS. HELM: May I publish, Your Honor?

THE COURT: You may.

BY MS. HELM:

Q. Mr. Van Vleet, who was this communication directed to?

A. It's directed to implanting physicians and clinicians responsible for the ongoing care of patients with inferior vena cava filters.

Q. Was this communication directed specifically to Bard?

A. No.

Q. Was it a communication specifically about Bard IVC filters?

A. No, it was not.

MR. O'CONNOR: Objection. Leading.

THE COURT: Overruled.

BY MS. HELM:

Q. Under the section -- let me see if I can find it.

In the section Summary of the Problem and the Scope, in the last paragraph, do you see where the FDA is discussing retrievable IVC filters?

A. Yes.

Q. And what does the FDA state about its concern about retrievable IVC filters?

A. They express concern that these retrievable IVC filters

intended for short-term placement are not always removed once a patient's risk for PE subsides. Known long-term risks associated with IVC filters include but are not limited to lower limb deep vein thrombosis (DVT), filter fracture, filter migration, filter embolization, and IVC perforation.

Q. After the FDA issued this communication in 2010, did Bard do anything to make sure doctors using its devices were aware of this FDA communication?

A. Yes.

MS. HELM: Scott, would you pull up 5923, please.

BY MS. HELM:

Q. And, Mr. Van Vleet, do you recognize this document?

A. I do.

Q. And what is this?

A. It's a letter that I authored for clinical caregivers or anybody involved in the treatment of patients with IVC filters.

Q. And does the letter bear your signature?

A. Yes.

MS. HELM: Your Honor, at this time I move to admit 5923, as redacted.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5923 admitted into evidence.)

MS. HELM: May I publish, Your Honor?

THE COURT: Yes.

BY MS. HELM:

Q. Mr. Van Vleet, was this letter given to doctors or hospitals that implant Bard IVC filters?

A. Yes.

Q. And what did Bard encourage doctors to do?

A. We encouraged physicians to review the FDA initial communication and to consider the risks and benefits of filter removal for each patient.

Q. And why did Bard provide this information to doctors?

A. Because we wanted them to understand that we supported the FDA and we supported surveillance of patients and following the patients.

Q. I'm going to shift gears one more time and talk to you about another document.

MS. HELM: Can we pull up 7960, please.

BY MS. HELM:

Q. Mr. Van Vleet, do you recognize this document?

A. I do.

Q. Was this document prepared either by you or at your direction while you were vice president of regulatory and clinical affairs at Bard Peripheral Vascular in 2010?

A. It was.

Q. Was this document maintained in the regular course of business at Bard?

A. Yes.

Q. And was it the regular practice of Bard to prepare information to give to doctors providing information about its products?
A. Yes.
Q. And what information was consulted in creating this handout?
A. This was a survey of published studies, either published studies that were conducted as part of the approval or clearance process for devices, or just any other study in the literature on a variety of IVC filter platforms, but also a published study on Bard IVC filter platforms.

MS. HELM: Your Honor, at this time I move to admit Exhibit 7960.

MR. O'CONNOR: Objection. Foundation. I don't see a date on this document.

THE COURT: Can you lay foundation on the timing, please?

BY MS. HELM:
Q. Mr. Van Vleet, do you recall approximately when this document was prepared?
A. 2010.

MS. HELM: Is there a second page, Scott?

BY MS. HELM:
Q. Mr. Van Vleet, on the second page in the bottom --

THE COURT: Just a minute.

What was that, Mr. O'Connor?

MR. O'CONNOR: No objection. I see the date now.

THE COURT: All right. 7960 is admitted.

(Exhibit No. 7960 admitted into evidence.)

MS. HELM: May I publish, Your Honor?

THE COURT: You may.

BY MS. HELM:

Q. Mr. Van Vleet, now that the jury can see it, explain to them what this is.

A. So this is an attempt to compare studies on different IVC filter systems, including Bard filter systems, and other competitive filter systems against each other wherever possible.

Q. Just so we're clear, this is -- is this information that Bard obtained through published literature about its IVC filters and other IVC filters?

A. Yes. On the back is -- are all of the references from where these data were derived.

Q. Okay. And did Bard -- and in this handout to doctors, Bard included the reported rate information from each of those published studies?

A. Yes.

Q. Mr. Van Vleet, does this include the Nicholson study?

A. It does.

Q. Why did Bard include the Nicholson study in a handout that

it was providing to physicians about published information regarding its filters and other filters?
A. Because if you're providing information to clinicians, you can't cherry-pick data that only suits your own purposes. So it's really important to be balanced and show the good, bad, and the ugly.
Q. And does this handout also provide information regarding studies for filters that were made by manufacturers other than Bard?
A. Yes. It includes data on the Celect filter by Cook option, by Allen, Tulip, et cetera, and OptEase.
Q. And why did Bard include information about other manufacturers' filters?
A. Because those are contextually -- those are filters that were available for sale at that period of time so it would be a fair comparison.
MS. HELM: Thank you. You can take that down.
BY MS. HELM:
Q. Mr. Van Vleet, during the ten-plus years that you were at Bard, did you become familiar with Bard's processes and procedures regarding taking corrective actions or addressing complications with its medical devices?
A. Yes.
Q. And were those policies and procedures also applicable to Bard's IVC filters?

A. Yes.
Q. During your time at Bard, if Bard determined that the risks of a benefit -- of a product outweighed the benefits, what type of actions would Bard take?
A. Bard could alert the practicing community, they could put a hold on the product, or they could remove the product from the market.
Q. Over your almost 11 years at Bard, did Bard ever make a determination that the G2, the G2X, or the Eclipse filters, that the risks of those filters outweighed the benefits?
A. No.
Q. Mr. Van Vleet, when you were vice president of regulatory and clinical affairs at Bard, did you have access to all information regarding the products for which you were responsible?
A. Yes.
Q. And you just used a term a few minutes ago, the good, the bad, and the ugly.
A. Correct.
Q. Did you have access to all of that information?
A. Yes.
Q. During the approximately ten-plus years that you were at Bard, did you ever feel that the risks of the G2, the G2X, or the Eclipse filters outweighed the benefits of those filters?
A. No.

MS. HELM: Thank you. I don't have any further questions at this time.

THE COURT: Cross-examination.

MR. O'CONNOR: Yes. Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. O'CONNOR:

Q. Hello, Mr. Van Vleet. My name is Mark O'Connor. How are you?

A. Good. Thank you.

Q. Thanks for coming down here today.

Mr. Van Vleet, you agree that Bard should always make patient safety a priority. It should come first; correct?

A. It always did.

Q. Bard should not expose a patient to an unnecessary risk of harm. Do you agree with that?

A. I would agree.

Q. The Eclipse was promoted and was sold and marketed as a permanent filter; true?

A. Yes.

Q. Meaning that, depending on the physician and the patient, that filter, like the G2 and the G2X, could be put in a patient for the duration of that patient's life; correct?

A. It could be. Uh-huh.

Q. And the patient and the doctor who had used it as a permanent device had the right to expect that the filter would

remain in place and do its job; true?
A. For as long as the doctor felt the patient needed it, correct.
Q. And if it was permanent, that meant do its job, stay in place for the duration of a patient's life; correct?
A. That's the correct expectation.
Q. And that filter, those filters, those three filters were being placed in patients who had life expectancies much longer than just ten years; true?
A. I believe so.
Q. Thank you.

The only design difference between the Eclipse and the G2 filter was that the Eclipse was electropolished; correct?
A. Correct.
Q. Now, the Eclipse filter did not contain caudal anchors; true?
A. The Eclipse filter did not -- I believe that's correct, yes.
Q. Caudal anchors are designed to reduce caudal migration; correct?
A. Correct.
Q. Bard understood as early as 2006 that caudal anchors could reduce caudal migration; true?
A. I was not an employee of Bard at that time.
Q. I think you testified to that, though. Do you want to go

to your testimony?
A. Sure.
Q. As long as you were at Bard, you knew Bard was aware that caudal anchors could reduce caudal migration; fair?
A. I believe so.
Q. Thank you.
And Bard knew from the EVEREST trial that migration could lead to tilt, perforation, and fracture in the Bard filters that were used in that trial; correct?
A. The complications in the EVEREST trial, yes, have been reported.
Q. And just so you and I are on the same page, a lesson Bard learned from EVEREST was that migration in the G2 filter could lead to tilt, perforation, and fracture; right?
A. There were a lot of hypothesized theories that were being evaluated about all of the complication modes that were seen.
Q. You were seeing different complications, several -- more than one complication in different patients; right?
A. In the EVEREST trial, in some cases there were multiple patients.
Q. And nowhere in the IFU did Bard say that the G2 migration can lead to perforation, tilt, or migration or fracture, did it?
A. It did not.
Q. Thank you.

The filter with caudal anchors became the Meridian; is that right?
A. It is.
Q. And caudal anchors made the Meridian 16 more times resistant to caudal migration than the G2X and the Eclipse; correct?
A. I don't know of the multiple, but if there is something you can show me, I can tell you if I've seen it before.
Q. That's what you understood; correct? That sound about right?
A. I don't know the multiple, but I know that there was an increased resistance in migration.
Q. You did know that the addition of caudal anchors would make the filter more resistant to caudal migration; true?
A. That was what was hypothesized, correct.
MR. O'CONNOR: Felice, can we show Exhibit 4896 real quick?
And Mr. -- Your Honor, I believe this is in evidence. May I publish?
THE COURT: 4896 is the number?
THE COURTROOM DEPUTY: It is.
THE COURT: Yes, you may publish.
MR. O'CONNOR: May I publish to the jury?
THE COURT: Yes.

BY MR. O'CONNOR:

Q. Mr. Van Vleet, you can see there are signatures dated August 9 -- 19, 2010. August 2010. Do you see that to the right?

A. I do.

Q. And there, back in 2010, Bard was testing the Meridian against the OptEase filter; right?

A. That's -- yeah. That's what the title says.

MR. O'CONNOR: Felice, can you put up Exhibit 5593?

I believe this is in evidence, Your Honor, subject to redactions.

THE COURT: What's the number?

MR. O'CONNOR: 5593.

THE COURT: Yes, it is. You may publish.

MR. O'CONNOR: Felice, go to page 2, second to last paragraph.

And highlight the last sentence in the last -- second to last paragraph, please. That last sentence, Felice.

THE WITNESS: Sure. It says: John, that would be me --

MR. O'CONNOR: I'm sorry. I'm talking to Felice.

THE WITNESS: Oh, I apologize.

MR. O'CONNOR: No, that's all right. I'm trying to control a couple different fronts here, Mr. Van Vleet, but thank you for your cooperation.

BY MR. O'CONNOR:

Q. I'll read it.

John said yes, but this is far out in the timeline. John said that Angela could expect caudal anchors project in Quarter 3 or Quarter 2 of 2010.

Now, did I read that correctly?

A. Yes.

Q. Thank you.

The point is, long before 2011, Bard was aware of caudal anchors and how caudal anchors could resist caudal migration; correct?

A. Correct.

Q. And, sir, during that period of time, Bard was developing a filter with caudal anchors; correct?

A. Yes.

Q. And Bard did not stop selling the G2, the G2X, or the Eclipse; is that correct?

A. Correct.

MR. O'CONNOR: Felice, would you please put up Exhibit No. 1940.

Your Honor, I believe it's in evidence. May we publish?

THE COURT: You may.

BY MR. O'CONNOR:

Q. And, sir --

MS. HELM: Excuse me, Your Honor. Object. This is cumulative. Mr. Van Vleet's already been cross-examined on this document.

MR. O'CONNOR: Your Honor --

THE COURT: Well, he hasn't been cross-examined before. You mean during his direct testimony?

MS. HELM: Yes, Your Honor. My objection is it's cumulative. He's already been questioned about this document.

THE COURT: Objection overruled.

MR. O'CONNOR: Felice, if you would, just highlight quickly "MDRs for G2 and G2X."

Very good. Thank you.

BY MR. O'CONNOR:

Q. All right. Do you see -- this is as of July 2010, Mr. Van Vleet. And do you see that the G2 as of July 2010 had 689 MDR reports?

A. I see that number, yes.

Q. MAUDE data reports.

And the G2X had 153; is that correct?

A. Yes, I see that.

Q. And the Eclipse wasn't even launched in 2010; correct?

A. Yes, correct.

Q. And already in 2010, the Eclipse is experiencing 14 of those MDRs; correct?

A. Yes.

Q. Now, earlier, when -- you discussed with Ms. Helm the August 9, 2010, FDA letter.

Do you recall that?

A. Yes.

Q. And the letter mentioned the number of complaints that the FDA had received, MAUDE data complaints.

Do you remember that statement in there?

A. I do.

Q. Did you go and look to see how many of those complaints were Bard complaints?

A. I believe the quality organization does that just routinely every month.

Q. You didn't, did you?

A. I did not, no.

Q. And so if you look at here, we have 337 plus 689 plus 153 plus 14. I didn't calculate it, but that's an awful lot of MDRs, isn't it?

A. It is.

Q. Thank you.

And that's just for Bard filters; right?

A. It is.

Q. And, sir, as we look at this document, Bard never included this information, how many complaints Bard was aware of with Bard filters, in any of its IFUs, did it?

A. No. That's not -- not something --

Q. Sir --
A. -- the FDA would agree with either.
Q. Sir, you didn't put in any IFU the number of complaints Bard was aware of; is that fair? Yes or no?
A. Only the ones that are reported in clinical trials.
Q. My question is different.
A. Okay.
Q. We're looking at a lot of MDRs here. You didn't put that information in an IFU, did you?
A. Nobody does that.
Q. Thank -- well, you didn't, did you?
A. No, I didn't.
Q. And one thing's for sure: You also didn't put in your IFU or any document to a doctor in 2010 or even 2011 a warning or an alert that Bard knew that caudal anchors would resist caudal migration, did you?
A. Not to my knowledge.
Q. But you knew caudal anchors would; right?
A. It was being tested at that time.
Q. And the other thing you didn't put in any warning, any document, any marketing information to any doctor was that Bard had a hypothesis that when its G2 filter migrated, it would lead to tilt, perforation, and fracture. That wasn't included in any information supplied to the medical community, was it?
A. I don't believe so.

Q. I just want to talk to you about Dr. Lehmann real quickly, please.

He was an independent consultant for Bard during your tenure at Bard; correct?

A. He was -- he definitely was.

Q. And he was originally intended to be the person who signed Bard's submission to the FDA reporting on the EVEREST trial; true?

A. He was going to sign the clinical study report section, correct.

Q. And you do recall that Dr. Lehmann did not want to include SIR guideline information in the Bard's EVEREST trial submission; right?

A. I do.

Q. And Dr. Lehmann didn't want to include SIR guideline information because that information, he felt, was intended for -- was not intended for anyone other than physicians. True?

A. Correct.

Q. And Dr. Lehmann did not believe it would be truthful and accurate for Bard to represent that the EVEREST trial demonstrated that the G2 was substantially equivalent to a similar device; true?

A. I believe he may have said that, yeah.

Q. And after getting the report back from Dr. Lehmann, you

requested that he be removed as a submitting author for the EVEREST trial report; correct?
A. I did.
Q. And the final report was ultimately sent to the FDA, and that report did include comparison data from the SIR guidelines; correct?
A. It did.
Q. Bard never told the FDA about Dr. Lehmann's concerns about including SIR guidelines in the EVEREST submission, did they?
A. I don't believe so.
Q. Now, sir --
MR. O'CONNOR: Put up Exhibit 4499, please, Felice. And if you'll look down --
May I display to the jury, Your Honor? I believe this is in evidence.
THE COURT: It is not in evidence.
MR. O'CONNOR: It is not?
THE COURT: No.
MR. O'CONNOR: Okay. I offer it into evidence.
MS. HELM: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit No. 4499 admitted into evidence.)
MS. HELM: May I see the next couple of pages on it, Mark?
MR. O'CONNOR: Pardon me?

MS. HELM: May I see the --

MR. O'CONNOR: Yeah.

MS. HELM: Is that the last page?

Thank you.

MR. O'CONNOR: All right. Go to the first page. Felice, just highlight "16 times improvement in caudal migration," would you, please.

BY MR. O'CONNOR:

Q. All right. Now do you see where I was talking about earlier? That's something Bard became aware of in its testing of the Meridian that started even before you came to Bard; right?

A. I don't know when it started, but it definitely is the 16 number that you discussed before.

Q. And Bard never warned doctors in 2008, 2009, or 2010 or 2011 that they should stop using --

MR. O'CONNOR: Oh, may I publish, Your Honor?

THE COURT: Yes.

BY MR. O'CONNOR:

Q. Bard never warned doctors in 2008, 2009, 2010, or even 2011 that they should stop using the G2, the G2X, or the Eclipse because they had a filter with caudal anchors coming soon, did they?

A. No.

MR. O'CONNOR: 4892, please.

BY MR. O'CONNOR:

Q. Do you recognize this as the Denali IFU?

A. Yes.

MR. O'CONNOR: Offer into evidence, Your Honor.

MS. HELM: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit No. 4892 admitted into evidence.)

MR. O'CONNOR: Display to the jury, Your Honor?

THE COURT: You may.

MR. O'CONNOR: And may we go to page 6? And, Felice, can you highlight the complication rates, please? And enlarge it.

BY MR. O'CONNOR:

Q. Turns out Bard did know how to put complication rates in its IFU, didn't they, Mr. Van Vleet?

A. I'm sorry. What's the question?

Q. Turns out when the IFU came around, Bard did figure out that it could put complication rates in its IFU. True?

A. It certainly -- they certainly are in the Denali IFU.

MR. O'CONNOR: All right. Thank you. I don't think I have any more questions.

THE COURT: Redirect?

MS. HELM: Can you leave that exhibit up, please, with the complication rates?

REDIRECT EXAMINATION

BY MS. HELM:

Q. Mr. Van Vleet, before the FDA would clear the Denali, did it require a clinical study of the Denali?

A. Yes.

Q. And is the IFU, are these the complication rates from that clinical study of the Denali?

A. Yes.

MS. HELM: Thank you. You can take it down.

BY MS. HELM:

Q. In the previous IFUs, did Bard also include complication information regarding the EVEREST study?

A. Yes.

Q. Mr. O'Connor asked you about MDRs, and that was a large number.

Do you remember that?

A. I do.

Q. Does Bard report all complications and all adverse events that it receives from patients or physicians?

A. Bard reports all information, all feedback from patients or physicians, even when they can't corroborate it.

Q. Does that sometimes relate to packaging?

A. Yes.

Q. Deployment?

A. Yes.

Q. Many things that aren't adverse events relating to the performance of the filter?
A. Yes.
Q. So if that number was all MDRs, would it include all of those reports, not just those relating to the adverse events we've been talking about today?
A. Absolutely.
MR. O'CONNOR: Objection. Leading.
THE COURT: Sustained.
BY MS. HELM:
Q. Mr. Van Vleet, that total MDRs, what would that include?
A. That would include anything that came from a hospital, a physician, even if a patient were to call in -- probably the silliest example is you change the number or you change the color on the box and I don't like it. That also is included as an MDR.
I can tell you, in the 11 years that I worked for Bard, I've never seen a company report more MDRs than Bard.
MR. O'CONNOR: Objection. Nonresponsive, Your Honor.
THE COURT: Overruled. That's the questioner's objection.
BY MS. HELM:
Q. Mr. Van Vleet, you had a professional disagreement with Dr. Lehmann?
A. I did.

Q. Did that professional disagreement with Dr. Lehmann in any way impact whether Bard provided all of the information to the FDA regarding the EVEREST study and the adverse events in the EVEREST study?

A. Absolutely not.

Q. Mr. O'Connor asked you on more than one occasion -- he got you to state, to agree, that Bard did not remove the G2, the G2X, or the Eclipse filters from the market.

Do you recall that?

A. I do.

Q. Based on your experience and your work at Bard, was there ever any reason, in your opinion, for Bard to remove the G2, the G2X, or the Eclipse filters from the market?

A. No.

MS. HELM: Thank you.

THE COURT: All right. Thank you, sir. You can step down.

(Witness excused.)

MR. ROGERS: Your Honor, could we approach briefly?

THE COURT: With three minutes to go?

MR. ROGERS: Yes, Your Honor.

THE COURT: Yes, you can.

MR. ROGERS: Okay.

THE COURT: You can stand up, ladies and gentlemen.

(At sidebar on the record.)

MR. ROGERS: Your Honor, given the time of day and the charge conference, would it be okay if we let the jury go so we can start? And we'll be glad to eat the time.

THE COURT: I'm going to charge you for your three minutes.

MS. HELM: Fine.

MR. ROGERS: Yeah, that's fine.

MS. REED ZAIC: And a bean.

(End of discussion at sidebar.)

THE COURT: We're going to break for the day, ladies and gentlemen. We will start tomorrow morning at 9:00 o'clock. As I've indicated, I believe we'll get the case finished by about this time tomorrow evening so that you'll be able to begin your deliberations on Thursday morning.

Please remember until then not to discuss the case. Don't do any research. And we'll look forward to seeing you tomorrow morning.

(Jury not present.)

THE COURT: Please be seated. Let me do the time calculation, counsel.

MR. O'CONNOR: Your Honor --

THE COURT: All right, counsel. As of the end of the day, plaintiffs have used 32 hours. Defendants have used 25 hours and 46 minutes.

MS. HELM: I'm sorry, Your Honor, do you mind

repeating that?

THE COURT: 25 hours and 46 minutes.

MS. HELM: And the plaintiff?

THE COURT: 32 hours.

MS. HELM: And 0 minutes?

THE COURT: And 0 minutes. Yeah, they had 24 minutes this afternoon, plus the 31.36 this morning. It comes out to exactly 32 hours.

Counsel for the defense, what are you planning to do in the morning in terms of additional evidence?

MR. ROGERS: Your Honor, we will be calling one last live witness and perhaps also have a video, but we should be resting tomorrow morning.

THE COURT: How long do you think your evidence will take?

MR. ROGERS: I would say certainly no more than two hours, and I think that's an outside limit.

THE COURT: Okay. Well, we'll just have to play it by ear in terms of when we start argument.

Plaintiffs, do you anticipate much in the way of rebuttal evidence?

MR. O'CONNOR: Your Honor, I haven't had a chance to meet with our team. I can't imagine anything time-consuming, if there's going to be any at all, but I would have to consult with everybody this evening.

THE COURT: All right. Well, when we get to the end of the evidence, I'll plan to instruct the jury; and then we'll see where we are in terms of argument and the lunch hour so that we try to make it as smooth as possible.

While I'm thinking of it, I would like all of you -- well, not all of you -- I would like whoever would be the relevant folks to plan on an 11:00 a.m. hearing on Thursday to talk about case management issues from here through the next two bellwethers. We've got to make sure we've got the dates set for the final pretrial conference, when motions are going to be due, et cetera. So please be prepared, if you would, to talk about that on Thursday at 11:00 while the jury is deliberating.

Okay. Let me get my jury instructions.

MS. HELM: Your Honor, may I be excused for just a minute?

THE COURT: Yeah.

MS. HELM: Thank you.

THE COURT: That's fine.

MR. O'CONNOR: Can I step out for five minutes, Your Honor?

THE COURT: I can't hear you, Mr. O'Connor.

MR. O'CONNOR: Sorry. I don't want to delay things. I plan to be with my group here, but I just want to step out for five minutes. Is that okay?

THE COURT: Yeah. Can we start without you?

MR. O'CONNOR: Yes, sir.

THE COURT: Okay. Mr. Rogers, Mr. North, do we need to wait for Ms. Helm to come back before we get started?

MR. NORTH: We do not, Your Honor.

THE COURT: All right.

MR. ROGERS: Your Honor, and just to -- I'm also going to slip out, and Mr. North is going to handle for us. But unlike Mr. O'Connor, I'm not coming back.

THE COURT: Okay. We filed proposed final jury instructions on September 27th, which was the end of last week.

What I'd like to do is find out first what comments you have on Instructions 1 through 12. And we particularly need to talk for a moment about Instruction No. 7.

Before we get to 7, let's just find out, plaintiffs, do you have comments on any of the 1 through 12 instructions other than number 7?

MR. GOLDENBERG: Hold on, Your Honor.

THE COURT: Pull the mic over, would you?

MR. GOLDENBERG: Sure.

Your Honor, I guess the only one that I would have a comment on is we just need to discuss if there were any charts and summaries actually admitted into evidence. I'm not really sure that there were. I think there were demonstrative exhibits used, but I'm not positive that number 9, charts and

summaries that have been admitted into evidence --

MR. O'CONNOR: Yes, there were.

MR. GOLDENBERG: There were? Okay.

THE COURT: Well, there was not a 1006 chart, was there?

MR. O'CONNOR: Well, I think we admitted a chart out of the medical literature today, and yesterday there was a graph that they admitted on sales.

THE COURT: But that's not what this is talking about. This is --

MR. GOLDENBERG: These are the charts that would only be for summary purposes.

THE COURT: Yeah, this is a 1006 chart.

MS. REED ZAIC: There was no 1000 chart entered.

THE COURT: All right. So I think you're right.

Any objection to taking out number 9?

MR. NORTH: None, Your Honor.

THE COURT: Any other comments from plaintiffs on 1 through 12 except for number 7?

MR. GOLDENBERG: No, Your Honor.

MR. NORTH: Only number 7, Your Honor. Nothing further.

THE COURT: Okay. Let's talk about number 7.

We've had, I think, three different witnesses testify, experts testify, who had involvement at the FDA, and they've

given FDA expert testimony.

Let me tell you what my thought is, and you can tell me what -- whether this is a bad idea. I propose that we leave the first paragraph the way it is, so it's clear that the parties don't have access to personnel at the FDA about their work at the FDA.

But then that we add a second paragraph that I just sketched out at lunch, so it's a little rough, but it would say something like this: Each side has presented expert witnesses to testify about FDA procedures and the 510(k) process in this case, but this testimony was based on the expertise of these witnesses and work they did after being retained as experts in this litigation.

To make clear that they're experts testifying about things they reviewed for this litigation, not people testifying about what they did at the FDA.

MR. NORTH: That's acceptable to the defendant.

MR. GOLDENBERG: We're okay with that, Your Honor. Thank you.

THE COURT: All right. So we'll give that instruction.

Let me ask you another question that occurred to me today. We admitted in evidence some internal FDA meeting notes. And I can see a juror hearing this instruction and saying, well, wait a minute. Somebody got access to documents

inside the FDA.

So I was wondering if we need to add a sentence that says something like: Internal FDA meeting notes have been admitted into evidence, but those were obtained through the Freedom of Information Act available to -- just so -- I don't know what the wording would be. The idea is that there's a way to get some but not most information that's internal to the FDA.

MS. REED ZAIC: So the distinction the Court is attempting to make clear to the jury is that these experts did not bring them with them in the course of their employment and activities?

THE COURT: Right. And the parties don't have a way to go get internal -- I think that's the point that plaintiffs want to make clear, is that you don't have the ability to depose FDA people, to inquire into the internal FDA deliberations. And I can see a juror saying, well, how did you get internal meeting notes?

It seems to me it needs to be made clear that some things, like those meeting notes, can be obtained through the Freedom of Information Act. Maybe that's unnecessary, but that's a thought that occurred to me today.

MR. NORTH: That's fine with the defendants, Your Honor.

MR. GOLDENBERG: Your Honor, I guess our position

would be that we're concerned that more highlights that testimony, and I think we would probably think it's unnecessary. I don't think there should be an instruction on that.

THE COURT: Okay. I'll leave it out then. I mean, this really is talking about testimony, and if somebody has that question and they choose to ask it, they can ask it as a juror.

Okay. Let's, then, talk about -- by the way, I'm obviously going to take off of each of these instructions the source line at the bottom of them before we finalize them.

Let's talk about Instruction No. 12. Any concerns about Instruction 12?

MR. GOLDENBERG: No, Your Honor.

MR. NORTH: None, Your Honor.

THE COURT: All right. How about 13?

MR. GOLDENBERG: None for the plaintiff, Your Honor.

MR. NORTH: None for the defendants, Your Honor.

THE COURT: All right. As you see, I adopted this odd wording of the preponderance of the evidence standard from Wisconsin. We tried to put it into sentences to make it as clear as possible, but I think we have to use it.

Okay. How about Instruction No. 14 from plaintiffs' side?

MR. GOLDENBERG: No objection, Your Honor.

THE COURT: From the defense?

MR. NORTH: Your Honor, we have no objection to number 14, but we do want to -- the major issue I'd like to talk about when it's appropriate is we believe number 14 standing alone is insufficient on the design defect, so we have a couple things we want to mention about additional instructions.

THE COURT: Let's talk about that now.

MR. NORTH: Okay, Your Honor.

We understand the Court's decision not to include the comments. But what we're concerned about -- comments to the Restatement, those instructions that were proffered based on those comments.

What we're concerned about is this Wisconsin pattern instruction is such a bare bones instruction. It's essentially just a recitation of the statute without any explanation. It's been developed by a committee, promulgated by the law school, a committee of judges, but there are no appellate decisions that we've found that have even discussed the statute.

I'm sure the courts wouldn't fuss with the statute, in part because it is just a recitation -- or the instruction because it's just a recitation of the statute. But the courts have not in Wisconsin addressed whether additional instructions need to be given.

Your Honor, we believe the terms in this instruction,

without further explanation, are vague and do not give the jury appropriate guidance. And those terms are the following: reasonable alternative design, reasonably safe, and unreasonably dangerous.

Your Honor, in our view, the term "reasonable" in this circumstance, without further explanation, is entirely subjective. You may have a juror on this panel who believes that any filter that has any complications, even a single one, is unreasonably dangerous without further guidance to that juror on what the concept means.

And I believe we all, sitting here, would agree that a single complication with a medical device under the law does not render it unreasonably dangerous.

Conversely, you might have some really more conservative jurors who believe that if a filter has a benefit to any -- even a single person, that it's reasonable. It's reasonably safe, because it gives a benefit to that person, even though the risks of that filter may overall far outweigh the benefits.

We believe that without further explanation, those terms are simply too subjective.

We know, of course, this Court's well aware that in this sort of circumstance -- and it is a difficult circumstance, we understand, with no guidance from the Wisconsin courts of any meaning. But this Court's task is to

try to predict what the highest court of Wisconsin would do if faced with these issues.

The Ninth Circuit has cited sources, of course, like intermediate appellate court decisions, decisions from other jurisdictions, statutes, treatises, restatements.

The key for these instructions for the jury, again, as I know the Court well knows, is that they need to adequately convey what the law is to the jury. And the Ninth Circuit has held that they must allow the jury to determine the issues presented intelligently and that sometimes, even if a juror -- a statement or instruction like this one is correct, it may not be sufficient without further guidance.

And the Ninth Circuit has had some cases where there are circumstances where they say specific terms need to be explained further. We believe that this is precisely that sort of circumstance.

Now, in the proposed jury instructions, Document 12438, we proposed four instructions on pages 46, 47, 48, and 49 that were taken directly from the comments of the Restatement (Third), which are one avenue, we believe, to give this jury further explanation as to what these terms mean.

Now, this morning we filed four other supplemental instructions. I don't know if the Court has had an opportunity to see those.

THE COURT: Yeah, I've seen them.

MR. NORTH: And I told Mr. Goldenberg that we were going to be filing those.

Your Honor, these are based on comments obviously from dissenting or concurring justices of the Wisconsin Supreme Court who were advocating before the legislature acted that they -- the state needed to adopt Restatement (Third) and move away from the consumer expectations test.

One of those decisions, the *Godoy* decision, is only a year or two before the legislature finally acted. We submit that those justices, particularly in the *Godoy* case, those justices' discussion of what the Restatement (Third) meant and the application of that would entail is extremely insightful as to the scope of the law. It's probably the best evidence we have there -- out there if we were going to further define these terms.

Now, all of this, I think, Your Honor, is so important for one reason. You read the statutory language on its face, and it doesn't say the words "risk utility." But everybody agrees that the Restatement (Third) involves a risk utility analysis.

The authors of the Restatement (Third), Professors Henderson and Twerski, made that very clear. The justices in the *Green* case, the dissenting Justice Sykes in the *Green* case, and in the *Godoy* case, the concurring justice, both make it clear that risk utility is at the heart of this particular

formulation, Restatement (Third).

There's nothing in the bare bones recitation of the statutory language itself that makes it clear. And therefore, we think it's important to let the jury know that.

Lastly, Your Honor, the fourth instruction we developed is taken from the *Green* case, or actually an older case, and that was --

THE COURT: What fourth are you talking about?

MR. NORTH: That we did today. The four that we did this morning.

THE COURT: Number 4 in this series that you provided? You provided several different instructions.

MR. NORTH: Right, okay. This is on page 5 of 7. It's called Proposed Instruction Re: Design Defect. I think several of them had the same name. But it lists five factors.

THE COURT: By the way, I'm told -- I haven't read them yet -- I'm told by Jeff that those five factors come from a Seventh Circuit case that got them from the Fifth Circuit in Minnesota. That's what the Seventh Circuit cited as the source of the five factors. Now, it was on an appeal from a Wisconsin case, but it wasn't looking at Wisconsin law.

MR. NORTH: Well, they were cited in the *Sumnicht versus Toyota* case, as I understand it.

THE COURT: They were cited in the concurring opinion; right?

MR. NORTH: No.

THE COURT: Show me where you're looking at in the citation.

MR. NORTH: I do not have that case with me, Your Honor, and I apologize. I do have the *Green* case where Justice Sykes, in the dissenting opinion, discusses those five factors from *Sumnicht*.

THE COURT: Well -- oh, I'm sorry, *Sumnicht*, that's right. That's the 1984 --

MR. NORTH: Right.

THE COURT: -- case. Right.

MR. NORTH: Justice Sykes, in her dissent in *Green*, cites back to those five factors that -- it said: This is the test we've articulated. And while we call it consumer expectations, at its heart, it's essentially a risk utility.

So that's other evidence or, I think, or another formulation that could be given to the jury. These are all proposals that we think one of them needs to be adopted to further explain to this jury what reasonable means under these circumstances.

MR. GOLDENBERG: Thank you, Your Honor.

I think that this has been a valiant effort by the defense, but I think that the pattern jury instructions are the most instructive here on what exactly the law is and how you're supposed to give instructions in this case.

It's been since 2011 that the statute has been changed in Wisconsin for strict liability, and there is nothing other than the Wisconsin jury instruction -- pattern instructions, which are updated every single year, to give you instruction as to how to advise the jury.

There's discussion in each of these -- in each of these Wisconsin JI Civil instructions, and nowhere does it say anything that the defense is advocating here.

I think, in particular, it's interesting that the case law that the defense is now citing is something that they already said had been overruled by the statute, like *Green*. But now they're trying to get it in in a different way.

Anything that they -- I looked at all four of their proposed instructions today, and each of them are based on dissents or concurring opinions in these cases that weren't even adopted by the majority in Wisconsin law. So this has never been adopted in Wisconsin law, in either case law or by statute.

So we respectfully submit that, yes, Wisconsin law is simple, and that is how it's laid out. And the -- just as the Court has said to both of us before, we're allowed to argue to the jury what we think reasonable is and what defective design is. And it lays out in the statute -- in the actual instructions themselves good information on what they should consider.

And so when they're looking at if a filter is defective, they have to look at the foreseeable risks of harm posed by the filter design that could have been reduced or avoided by adoption of a reasonable alternative design. And they have to look at the omission of the alternative design that could render the product not reasonably safe. So there is a definition in there of what they're supposed to look at.

And so we submit, Your Honor, that, respectfully, this is the way the statute reads. They've never adopted the Restatement. They've never adopted any of the kinds of instructions that have been advocated by the defense, and we would ask that they be read as you gave them to us.

THE COURT: Okay. I understand your positions. I want to think about this a bit more. It seems to me my task, what I ought to be doing in this case, is replicating as closely as I can the kind of instructions you all would get in federal district court in Wisconsin.

My memory is -- I haven't looked at these cases since one of my earlier rulings in this case -- that even among the federal judges in Wisconsin, there's disagreement on whether the instructions are a part, with some federal judges saying -- I'm sorry, the comments to the Restatement are not part of Wisconsin law.

It's a tough task to do the predicting that I'm called upon to do, but I will think about it a bit more and I'll let

you know in the morning my decision.

MR. NORTH: If I could just make one point, Your Honor.

My recollection is -- and I believe I recall the case you're talking about. My recollection is the case said it's not clear whether the Wisconsin law has adopted those comments, but in any event, it would not matter here.

I'm not sure there's been a direct ruling that said Wisconsin doesn't adopt the comments.

THE COURT: Okay. Fair point.

All right. Let's talk about Instruction No. 15, which is the negligent design case -- claim.

Are there comments from plaintiff?

MR. GOLDENBERG: Yes, Your Honor. We think that there is some wording that just slightly needs to be reorganized, if you could go to Wisconsin JI Civil 3240 and look at the actual language.

THE COURT: Hold on --

MR. GOLDENBERG: Do you have that in front of you?

THE COURT: Hold on just a minute.

MR. GOLDENBERG: And I'm talking about the pattern instruction, of course.

THE COURT: Right. Yes, I've got it.

MR. GOLDENBERG: Okay. If you look at the bottom of it, the last sentence reads: Failure of the manufacturer to

perform any such duty constitutes negligence.

If we look at the last sentence of your -- of the instruction that was given to us, somehow that's kind of buried into the second paragraph, and the last sentence is: A manufacturer is charged with knowledge of its own methods.

I'm not sure if that got transposed, but I think that the "A manufacturer is charged with knowledge of its own methods of designing its product and the defects in such methods, if any," should go as the last sentence of paragraph 3, and then the final sentence as it reads in the instruction should be, "Failure of the manufacturer to perform any such duty constitutes negligence."

Otherwise it looks as if -- it looks as if that last sentence isn't considered negligence if they don't do it.

THE COURT: All right. I understand that point.

Do defendants have a comment on that?

MR. NORTH: Your Honor, both sentences are in your instruction. I'm not sure it really matters as to the order.

THE COURT: Do defendants have comments on this instruction?

MR. NORTH: No, Your Honor. I'm sorry.

THE COURT: Okay. Give me just a second.

Here was the thinking in the placement of that sentence. You have 3240 there?

MR. GOLDENBERG: I do.

THE COURT: The statement in 3240 is included in 3240 with the preceding paragraph, "It is the duty of the manufacturer." So it's specific to that duty instruction.

But what we did in this instruction, because we thought it would be helpful to the jury, was we also included the general definition of negligence.

MR. GOLDENBERG: I thought that was smart.

THE COURT: Well, so the thought was, since that sentence that you've highlighted is specific to the manufacturer's duties, we ought to put it into the paragraph in this combined instruction that talks about manufacturer's duties. Otherwise, we are applying that sentence to anything that might come before that paragraph that it doesn't apply to in the standard instruction.

That was -- that was the reason for putting it right after that paragraph. And that general charge about what the manufacturer is charged with wasn't really talking about duties, so we thought that could be broken out separately.

So that was the thought. I'm interested in your --

MR. GOLDENBERG: Yeah. I still think, Your Honor, it seems like it's part of that paragraph. If we look at 3240, it's still -- that last sentence is really part of the second paragraph.

And, I mean, if you wanted to put that "Failure of the manufacturer to perform any such duty constitutes negligence"

in the same paragraph, we'd be okay with that. But I think it should be the last sentence.

THE COURT: So you would say, take -- on my proposal 15, take the last sentence, "A manufacturer is charged," and put that before "The failure of a manufacturer to perform" so it's in the same order as the standard instructions?

MR. GOLDENBERG: Yes.

THE COURT: Mr. North, what do you think?

MR. NORTH: No objection, Your Honor.

THE COURT: Okay. I also noted that the wording is a little different in the failure to perform. We wrote it "Failure of the manufacturer to perform such duties," rather than "any such duty," which is in the standard instruction. We should follow the standard instruction.

So what I will do is I will move that last sentence and make it the next to last sentence in the paragraph above it, and I will change what will then become the last sentence to refer to "any such duty" rather than "such duties."

MR. GOLDENBERG: That would be fine, Your Honor. Thank you.

THE COURT: Okay. How about Instruction 16? Any comments from plaintiff?

MR. GOLDENBERG: No objection to that, Your Honor.

THE COURT: Defendants?

MR. NORTH: No objection, Your Honor.

THE COURT: All right. How about -- well, let's first talk about objections to Instruction 17 and then talk about how we reflect my Rule 50 ruling in that instruction.

Are there objections to Instruction 17 as it was proposed?

MR. GOLDENBERG: No, Your Honor.

THE COURT: Defendants?

MR. NORTH: Your Honor, just a couple. In the third paragraph, the last sentence, we think, to be more precise, where it says "certain to suffer in the future as a result of," it should say "caused by," since we'll have instructed on proximate cause earlier.

THE COURT: So you would say --

MR. GOLDENBERG: I'm sorry, Richard. Which paragraph are you talking about?

MR. NORTH: Third paragraph, last sentence. We would strike the words "as a result of" and just put "caused by."

THE COURT: So it would say: Reasonably compensate Mrs. Hyde for the injuries she has suffered to date and is reasonably certain to suffer in the future caused by the defective or negligent design?

MR. NORTH: Yes.

MR. GOLDENBERG: I would disagree with that, Your Honor. I think it reads how it should read. When it says "is

reasonably certain to suffer in the future as a result of defective or negligent design," I think that that's -- that reads exactly how it should. I mean --

THE COURT: Okay.

MR. GOLDENBERG: I especially think, if there's going to be in a special verdict form already, the word -- I think we've already used the word "cause," you know, defined "cause" actually in the special verdict form. I don't think there's any reason to change this part of the instruction.

THE COURT: The "as a result of" language comes from the Wisconsin standard instructions. It's Instruction 1766, and we had to modify it a bit, but the language in the second paragraph of that standard instruction talks about damages suffered as a result of. That's where we got the language.

THE LAW CLERK: I think defendants proposed it in their instructions.

THE COURT: I'm told defendants included it in your proposed instruction as well, which I didn't pick up on.

MR. NORTH: I'm sorry, Your Honor?

THE COURT: Apparently you proposed it as well in your instruction, Jeff tells me.

MR. NORTH: Oh. Your Honor, I apologize.

THE COURT: Well, I'm not going to include it for that reason, but I am going to include it because -- yeah, it actually is in defendants' proposal.

It's in the standard instruction, so I'm going to leave it the way it is.

Any other objection to 17 from defendants?

MR. NORTH: None, Your Honor.

THE COURT: Okay. On the Rule 50 motion --

MR. GOLDENBERG: Oh, Your Honor, I did notice one thing. If we turn to the second page of that --

THE COURT: Yes.

MR. GOLDENBERG: I'm just going to ask my team something really quick.

So I think we can take out -- I don't think we actually put in any billing statements, Your Honor, for healthcare services.

THE COURT: So the bracketed language at the top would come out?

MR. GOLDENBERG: You can subtract that, yes.

THE COURT: Any objection from defendants?

MR. NORTH: None, Your Honor.

THE COURT: Okay. Good catch. We'll take that out.

So here is my thought with respect to the Rule 50 motion.

The things that I have granted judgment on would be the cost of the future defibrillator -- I always lose track of where the R is supposed to fall in that word.

MR. GOLDENBERG: Try saying arrhythmia after that too.

THE COURT: I know where the R comes in arrhythmia. I'm okay with that.

Also any pain or suffering associated with future arrhythmia, because Dr. Muehrcke was -- said future arrhythmia is only a possibility, but not fear of future arrhythmia, because the Wisconsin case says fear of a possible complication is compensable.

So I guess the question is whether either side sees my ruling differently. I know plaintiffs disagree with it, but as to where we draw the line in light of my ruling, does that make sense?

MR. GOLDENBERG: It does. Certainly we understand your ruling, Your Honor. We would not be arguing in our closing any costs for either the arrhythmia or the defibrillator, but we certainly would be arguing the fear of having an arrhythmia in the future or having a defibrillator.

I think it highlights the testimony too much if we have an instruction. I'm not really sure -- I wrote out a couple instructions myself to see how I thought it would look, and I didn't like any of them.

I'm really not sure what instruction would be --

THE COURT: Well, here's my --

MR. GOLDENBERG: What would flag it.

THE COURT: I understand that point. Here's my concern. I think it was Ms. White, your expert, put hard

numbers up, a cost estimate of what it will cost to implant the defibrillator. That got into the jurors' notes.

It seems to me if I don't tell them that that cost that an expert testified to is not recoverable, then it may well get into the damages when I've ruled it shouldn't be.

MR. NORTH: Your Honor, sitting in the back of the courtroom, I was trying to come up with some language, and I've got something to propose if I could hand it out.

THE COURT: Yeah, that's fine.

MR. GOLDENBERG: Can I just talk with my team for a second?

THE COURT: Yeah, sure.

MR. NORTH: The second page is moot, Your Honor, the point I had there.

And, Your Honor, I would also note for the record that --

THE COURT: Let's wait till they finish talking so they can hear what you say.

MR. GOLDENBERG: Your Honor, I think our thoughts might be that we might be able to work with something like this, but we might want to do it on a stipulation. I think that that would be -- it would highlight less the issue itself, and maybe we could say something -- again, I'm going to have to think this out for a minute, but maybe we can say something where "The parties have stipulated as follows," and say

something after that.

I just think that that might be trying to highlight -- this is why I had a concern about having an instruction at all, is that, you know, when you say, "However, regardless of the evidence," I mean, it makes it sound like whatever was presented was unacceptable or, you know, something along those lines.

So I think if you're inclined to give an instruction, I think we might want to try to work out something that would say "The parties stipulate" and say something after that.

THE COURT: What are your thoughts?

MR. NORTH: Your Honor, I respectfully don't believe that's sufficient. There are parts of this instruction that we did not tamper with, for example, about future pain and suffering, because of the Court's ruling. And because there are some elements of this instruction that properly, under the Court's order, advises the jury they can present or award damages for some future issues, I think it needs to be coupled with a statement from the Court in the instruction as to what they can't do. And this is the language taken from your order.

MR. GOLDENBERG: If that was the case, Your Honor, I think it might want to read something like this: However, you should not award any damages for the cost of a defibrillator or any future medical costs associated with cardiac arrhythmias.

THE COURT: Yeah, that makes the same point. If it's

clear, I don't think I need to say "regardless of evidence you've received" if I'm telling them.

What I wondered was whether that leaves a question in the jurors' mind as to why, since they heard evidence, and whether I should say something like, "However, I have concluded as a legal matter that you should not award," so they understand it's a legal ruling. It's not a comment on the evidence. It's not me weighing in on what evidence you should or should not consider. I don't know if that's a good idea or not.

MR. GOLDENBERG: I think that just highlights it again, Your Honor. I think we would be more comfortable with just the concept of -- I mean, the instruction seems clear. "However, you should not award any damages for the cost of a defibrillator or any other medical costs associated with future cardiac arrhythmias."

MR. NORTH: Your Honor, I think what the Court proposes is probably just a more artful way of saying what I was trying to imply with the statement, "regardless of the evidence." They have heard evidence, and it went unchallenged. And I think they need to understand emphatically that they can't award damages for that, whether it's because we state specifically because the Court's ruling or emphasize to them that that's the rule here regardless of what they've heard.

MR. GOLDENBERG: Your Honor, I think there's even a

Supreme Court case that says that the jurors are presumed to follow the Court's instructions.

THE COURT: Oh, there's lots of cases that say that.

MR. GOLDENBERG: What?

THE COURT: There's lots of cases that say that.

I think what I'm going to do is just give a clear instruction as it's been proposed that says, "However, you should not award any damages for the cost of a defibrillator or any other medical costs or injuries associated with future cardiac arrhythmias." It's very clear that they shouldn't.

MR. GOLDENBERG: I think the injuries are something, though, that -- if we're allowed to argue the fear of, that sounds like that's an injury, isn't it?

THE COURT: Yeah, potentially. So "any other medical costs associated with future cardiac arrhythmias."

MR. GOLDENBERG: Right.

THE COURT: I think that captures the Rule 50 ruling.

Do you agree, Mr. North?

MR. NORTH: I thought your ruling was slightly more -- I understand the caveat about pain and suffering. I thought the Court was saying that she just can't recover anything but pain and suffering for any future cardiac arrhythmias.

THE COURT: The only other thing would be medical costs, right? And I'm telling them here you can't award medical costs for future arrhythmias.

MR. NORTH: I would respectfully disagree. There's future impairment or -- and other things of that nature that are not exactly pain and suffering, I think.

THE COURT: What about a current fear of a future arrhythmia? Is that an injury associated with future cardiac arrhythmias? Probably. I hate to start parsing this so closely that I say what kinds of injuries you can or can't recover.

MR. NORTH: I would note that we left in the language, the earlier language as far as pain and suffering does talk about future pain and suffering. It's not specific to cardiac arrhythmias, but it does talk about future still.

THE COURT: All right. I want to think about this a bit more. I understand your positions.

Okay. Let's turn to Instruction No. 18. Any comments from plaintiff?

MR. GOLDENBERG: Your Honor, we disagree with the concept of having to discount present value, but we understand it and we will not object to it.

THE COURT: Okay. Any comments on that from defendants?

MR. NORTH: No comments, Your Honor.

THE COURT: All right. How about number 19? Any comments from plaintiffs?

MR. GOLDENBERG: Your Honor, I do have a question for

you. I think that this was --

Well, hang on one sec. I just need to talk to my team for a minute.

MS. REED ZAIC: Referring back to 18, Your Honor.

MR. GOLDENBERG: Your Honor, honestly -- we can leave it. We're fine. No objection.

THE COURT: Okay. We'll leave it. Hold on just one second.

All right. Number 19. Any comment from plaintiffs?

MR. GOLDENBERG: No, Your Honor.

THE COURT: Defendant?

MR. NORTH: The only comment for the record, Your Honor, is we would just object to any instruction being given on that based on the Rule 50 motion.

THE COURT: All right. That objection is preserved.

How about number 20?

MR. GOLDENBERG: Can you repeat yourself? I'm sorry.

THE COURT: Number 20.

MR. GOLDENBERG: Number 20, we have no objection, Your Honor.

MR. NORTH: No objection, Your Honor.

THE COURT: 21?

MR. GOLDENBERG: No objection.

MR. NORTH: No objection, Your Honor.

THE COURT: 22?

MR. GOLDENBERG: No objection, Your Honor.

MR. NORTH: Your Honor, again, for the record, only an objection based on any charge being given based on the Rule 50 motion.

THE COURT: All right. 23?

MR. GOLDENBERG: No objection, Your Honor.

MR. NORTH: Your Honor, we had already submitted this to the Court earlier. We would only object to the third paragraph. I understand that's part of the pattern instruction, but I think the concept of a middle burden is much too obtuse.

THE COURT: Well, frankly, I agree with you. I don't know why -- I don't know why Wisconsin does that, but I don't know where they came up with the other wording for their burdens.

MR. GOLDENBERG: I think, Your Honor, the concept is they just want to distinguish between the two burdens, and that's the best way they could come up with doing so. I'm not saying it's a brilliant instruction either, but I think that's the way it's written.

THE COURT: All right. We'll leave 24 the way it is.

Any comment on any of the remaining instructions other than Instruction A at the end? That is, any of the deliberation procedure instructions?

MR. GOLDENBERG: We have no objection to the remaining

instructions, Your Honor.

MR. NORTH: No objection, Your Honor.

THE COURT: Okay. How about Instruction A, which is the instruction that I'll give if we get to the punitive damages phase?

Any comments from plaintiffs?

MR. GOLDENBERG: Let me just pull that out, Your Honor. I'm sorry.

No objection, Your Honor.

MR. NORTH: No objection other than any charge on punitive damages.

THE COURT: Right. Okay.

How about comments on the proposed verdict form from plaintiffs?

Mr. North?

MR. NORTH: Your Honor, I had a couple of things just on the instructions that weren't given, just to state for the record.

THE COURT: Okay. Yeah, that's fine.

MR. NORTH: We would object to the Court's decision not to instruct on the compliance presumption that the Court has already ruled against us on, and we would also object if the Court decides not to do any of the four instructions on the Restatement comments that I mentioned earlier.

The last thing, Your Honor, is the proposed

instruction regarding that inherent characteristic defense. The Court denied summary judgment on that, but I don't know that the Court granted summary judgment against us on that. And we thought that the standard instruction on that should be given.

THE COURT: Do you remember the number on that?

MR. NORTH: Your Honor, in our submission -- oh, the number of the pattern charge?

THE COURT: No, I'm sorry. Where was it in your submission?

MR. NORTH: It was Document 12438, and it was page 50 of 71, I believe. Yes.

THE COURT: Yes. Okay.

My memory, Mr. North, is that the cases that were cited in summary judgment on this issue was -- I think it was a lead paint case where you couldn't make the paint without the lead, and some sort of a flammable sealant that you couldn't make without making it flammable, the idea being that you can't make the product without the characteristic. Is that right? Or am I thinking of the other ones?

MR. GOLDENBERG: You're close, Your Honor, if you want me to let you know. I mean, it was a -- this was a -- I think you're talking about the *Godoy* case, right? This is the white lead carbonate case?

THE COURT: Right.

MR. GOLDENBERG: Yeah. And that was where the characteristic of the product itself was something that was so critical that they didn't find it defective.

MR. NORTH: The *Godoy* case predated the statute by a couple of years.

THE COURT: Well, let me -- I understand what you said, Mr. North.

What is the plaintiffs' view? I see the objection you stated on page 50. Do you want to add to that?

MR. GOLDENBERG: We have nothing to add, Your Honor. That's our objection.

THE COURT: Okay. I will look back at that again and think about what's been said.

Did you have any other comments on instructions, Mr. North?

MR. NORTH: Nothing further, Your Honor.

THE COURT: Okay.

MR. GOLDENBERG: Your Honor, I do want to mention, too, we briefed that in our trial brief as well. So if there's anything more you want to look at, it's in our trial brief as well.

THE COURT: Okay. How about comments on the verdict form?

MR. GOLDENBERG: Your Honor, our thoughts are that you did a good job on this. We -- our only concern are that we're

putting instructions into the jury verdict form. The "Do you find by greater weight of the evidence to a reasonable certainty" is certainly the law. But I don't see that in the Wisconsin pattern instructions, and it seems to emphasize --

THE COURT: You don't find that -- I mean, that language is right from the pattern instructions. That's their definition of preponderance of the evidence.

MR. GOLDENBERG: If I could just pull out --

THE COURT: You mean a Wisconsin pattern jury form?

MR. GOLDENBERG: Yeah, the pattern jury form.

THE COURT: Okay. You said instructions.

MR. GOLDENBERG: It's certainly consistent with Wisconsin law. I'm not suggesting that. It's just not usually --

THE COURT: Well, let me tell you why it went in.

MR. GOLDENBERG: Sure.

THE COURT: It went in because in our previous verdict forms, we said "Do you find by a preponderance of the evidence" in each of the questions. We replaced that with the Wisconsin definition of preponderance of the evidence.

But I'm happy to hear your argument on that.

MR. GOLDENBERG: Our only thoughts are, Your Honor, that because this is -- you know, you're reading the instruction specifically to them about greater weight, you're reading an instruction specifically to them about what the

burdens are, that we submitted the instruction simply as, you know, the -- we did not put in, in every instruction, "Do you find by the greater weight of the evidence to a reasonable certainty." We just simply asked the question.

So we would submit that that is the way Wisconsin does it in their pattern instruction for verdict, and we would ask that that be allowed. I think it just overemphasizes specific instructions. I certainly understand that's the law. We just think it -- we could put lots of instructions into the jury verdict form that we do not.

THE COURT: All right.

MR. NORTH: Your Honor, we believe it's very important to have this language in, particularly because you have two different burdens of proof at work in one verdict form. You've got the greater weight of the evidence there and then on the punitive damages, you have the clear, satisfactory, and convincing.

And I think it's necessary to make that distinction. We've done so in the Jones and Booker case without problems, and I think that needs to be there to make that clear.

THE COURT: All right. I understand the parties' positions. I've always been of the view that we should put a burden of proof in the question when we've got more than one burden of proof in one verdict form. And I feel the same way here, even though I don't like the Wisconsin wording, so I'm

going to stick with that verdict form.

Are there other matters that we need to address before we break?

MS. HELM: Your Honor, I understand that we're to come in at 8:00 o'clock tomorrow morning to review the exhibits?

THE COURT: If Traci says so.

MS. HELM: Actually, it was reported to me that Nancy said so.

THE COURT: Well, then you've got two good authorities on it.

MS. HELM: And then, Your Honor, I don't know if there's any further discussion we need to have about Exhibit 6061 and 6064. Those were the two that Mr. Lopez objected to, and you told us to go back and do our homework. And I've done mine, so I'm prepared to address those if there need be.

THE COURT: Yeah. I did say that I wanted to find out what had happened in Jones. You want to go ahead and address that?

MS. HELM: Yes, Your Honor.

6061 was admitted into evidence subject to redactions requested by the plaintiffs. Their objection was that it was a hearsay objection.

We have gone back and verified that it was indeed -- in fact, in the transcript it says it's admitted subject to the

redactions. And Mr. Lopez says he's making no concessions on the redactions.

And we didn't necessarily agree with the redaction, but it didn't impact the substance of the document, so 6061 was admitted redacted in Jones, and the redaction in that document was requested by the plaintiffs.

6064 was also admitted redacted in Jones. Those redactions were at our request. They were agreed to by the plaintiffs. And that long evening where we kept Traci here much too late, we went back and forth on a number of redactions. We removed some, we added some, but it was admitted redacted in Jones.

And we actually have maintained those as admitted Jones exhibits, and those are what we pulled for in the Hyde case.

THE COURT: All right. Do plaintiffs have any different view of the history?

MS. SMITH: No, Your Honor.

So those were redacted in Jones, and we had an opportunity to go back and look at them. My only comment was, is I think it was done at the eleventh hour and that there are times, including that document, where things were beyond the scope of the initial order.

For example, in that document, it only talks about Recovery deaths and it doesn't relate to migration.

THE COURT: Well, I understand that. When I was talking back and forth with Mr. Lopez on this issue, the request that he made was to strike 6064 and 6061 from the record and any testimony related to it.

As we talked, he then, I think, took the view that instead what he wanted was to remove the redactions and have them admitted without the redactions. And then he changed back and said the motion he was standing on was to strike those two documents.

And I said -- this was at the 15-minute discussion before we brought the jury in after the break -- that if, in fact, these were the redactions in the Jones case, I wasn't going to strike the documents.

And it sounds like they were the redactions, so I'm not going to strike the documents. And that's what had been requested.

All right. Are there other matters that we need to address?

All right. I will come in at 8:30 in the morning, and we'll get started again. Thank you all.

MR. NORTH: Thank you.

MR. GOLDENBERG: Thank you, Your Honor.

(Proceedings adjourned at 5:26 p.m.)

C E R T I F I C A T E

I, JENNIFER A. PANCRATZ, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 3rd day of October, 2018.

s/Jennifer A. Pancratz
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC